UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **November 23, 2026**

DOGWOOD THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-39811**	**85-4314201**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

44 Milton Avenue **Alpharetta, GA**	**30009**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code **(866) 620-8655**

(Former Name or Former Address, if Changed Since Last Report) Not Applicable

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	DWTX	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On November 23, 2026, the Company issued a press release announcing the positive top-line results from its randomized, double-blind, placebo-controlled Phase 2b trial evaluating Halneuron® administered subcutaneously in cancer survivors with moderate-to-severe chemotherapy-induced neuropathic pain ("**CINP**"). A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

On November 23, 2026, the Company updated its corporate presentation. A copy of the corporate presentation is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K. In addition, the Company prepared a corporate presentation outlining the positive results from its Phase 2b trial that may be used by the Company from time to time with investors, analysts, collaborators or other third parties. A copy of this presentation is furnished herewith as Exhibit 99.3 to this Current Report on Form 8-K. The information set forth in this Item 7.01 of this Current Report on Form 8-K and in the attached Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3 is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On November 23, 2026, the Company announced top-line results from its randomized, double-blind, placebo-controlled Phase 2b clinical trial evaluating Halneuron® administered subcutaneously, in cancer survivors with moderate-to-severe CINP. The trial was conducted at 27 sites in the United States and randomized 239 patients 1:1 to receive Halneuron® (n=120) or placebo (n=119). Patients were scheduled to receive eight subcutaneous injections of Halneuron® or placebo over a two-week treatment period, with the primary endpoint assessed at Week 4. The trial enrolled patients with neuropathic pain secondary to prior treatment with neurotoxic chemotherapy agents, including platinum-based compounds and taxanes. Mean baseline pain scores on the 11-point Numeric Pain Rating Scale ("NPRS") were 6.06 for Halneuron®-treated patients and 6.00 for placebo-treated patients, and the mean duration of CINP was approximately 5.6 years and 4.4 years, respectively. Overall, 51.7% of Halneuron®-treated patients and 57.1% of placebo-treated patients were receiving background concomitant pain medication, including gabapentinoids (39.2% and 42.9%), duloxetine or tricyclic antidepressants (20.0% and 21.8%) and opioids (13.3% and 10.9%), yet still qualified for having moderate-to-severe CINP.

The trial met its prespecified primary endpoint, the proportion of patients completing the study and achieving a 50% or greater reduction from baseline in the weekly average of daily 24-hour recall pain intensity scores, as measured by the NPRS, to Week 4. 23.3% of patients receiving Halneuron® achieved the primary endpoint, compared with 9.2% of patients receiving placebo (treatment difference of 14.1%; p=0.003). Halneuron® demonstrated a statistically significant improvement versus placebo on the primary endpoint measure at every study week.

Week 4 Efficacy

Endpoint	Halneuron® (N=120)	Placebo (N=119)	p-value
Primary Endpoint			
≥ 50% NPRS responder rate at Week 4	23.3%	9.2%	p=0.003
Key Secondary Endpoints			
Global assessment – overall neuropathic pain	30.8%	18.5%	p=0.027
Global assessment – overall numbness and tingling	30.0%	17.6%	p=0.025
Global assessment – overall quality of life	26.7%	12.6%	p=0.006
≥ 50% reduction in pain interference	25.8%	14.3%	p=0.026

Halneuron® achieved statistical significance versus placebo on key secondary global assessment endpoints of overall neuropathic pain (p=0.027), overall numbness and tingling (p=0.025) and overall quality-of-life measures (p=0.006). In addition, the proportion of patients achieving a 50% or greater reduction in pain interference with activities at work, leisure or home was also significant (p=0.026). Reductions in pain were observed in patients receiving Halneuron® alone and in patients receiving Halneuron® on top of background pain medications, including opioids, gabapentinoids and duloxetine or tricyclic antidepressants. Detailed analyses of secondary endpoints will be reported following completion of ongoing statistical review.

Halneuron® was generally well tolerated, and more than 95% of randomized participants completed the study. Treatment-emergent adverse events ("TEAEs") were reported in 90.0% of patients receiving Halneuron® and 54.6% of patients receiving placebo, and were generally mild to moderate in severity. The most frequently reported TEAEs in the Halneuron® group versus placebo were oral paraesthesia (70.0% vs. 7.6%), oral hypoesthesia (35.0% vs. 1.7%), paraesthesia (23.3% vs. 8.4%), headache (15.8% vs. 9.2%), nausea (15.0% vs. 6.7%), hypoesthesia (11.7% vs. 2.5%), fatigue (9.2% vs. 1.7%), dizziness (8.3% vs. 3.4%), increased blood pressure (6.7% vs. 0.8%), dysgeusia (6.7% vs. 1.7%) and somnolence (5.8% vs. 0.8%). Two serious adverse events (one possible related to study drug) were reported in Halneuron®-treated patients and 0 in placebo-treated patients. TEAEs leading to discontinuation occurred in 2.5% and 1.7% of patients in the Halneuron® and placebo groups, respectively. The safety profile observed was generally consistent with that reported in previous clinical studies of Halneuron®.

Forward Looking Statements

This Report on Form 8-K contains statements which constitute forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. These forward looking statements are based upon the Company's present intent, beliefs or expectations, but forward looking statements are not guaranteed to occur and may not occur for various reasons, including some reasons which are beyond the Company's control. For this reason, among others, you should not place undue reliance upon the Company's forward looking statements. Except as required by law, the Company undertakes no obligation to revise or update any forward looking statements in order to reflect any event or circumstance that may arise after the date of this Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1*	Press Release, dated November 23, 2026.
99.2*	Corporate Presentation, dated November 2026.
99.3*	Presentation, dated November 2026.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

* Furnished Herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

DOGWOOD THERAPEUTICS, INC.

By: /s/ Angela Walsh
Name: Angela Walsh
Title: Chief Financial Officer, Corporate Secretary and Treasurer

November 23, 2026

Exhibit 99.1

Dogwood Therapeutics Announces Halneuron® Meets Primary Endpoint with Statistically Significant Pain Reduction vs. Placebo in Phase 2b Study of Chemotherapy-Induced Neuropathic Pain

- Primary endpoint achieved: 23.3% of Halneuron® patients achieved a 50% or greater reduction in pain vs. 9.2% on placebo (p=0.003) -

- Statistically significant improvements observed in neuropathic pain symptoms (p=0.027), numbness and tingling (p=0.025), and quality-of-life measures (p=0.006) -

- Halneuron® treatment demonstrated a statistically significant improvement over placebo in the proportion of CINP patients pain interference by 50% or greater with activities at work, leisure, or home over placebo (p=0.026) -

- Treatment benefit was observed in patients with an average CINP duration of approximately five years and whether used alone or with background pain medications -

- Halneuron® was generally well tolerated; 4.2% discontinuation rate, identical to placebo -

- Company to host investor call today at 8:30am Eastern Time -

ALPHARETTA, Ga., November 23, 2026 -- Dogwood Therapeutics, Inc. (Nasdaq: DWTX) ("Dogwood" or the "Company"), a company that focuses on developing potential first-in-class, new non-opioid medicines to treat pain and neuropathy, today announced positive top-line results from its randomized, double-blind, placebo-controlled Phase 2b trial evaluating Halneuron® administered subcutaneously in cancer survivors suffering from chemotherapy-induced neuropathic pain ("CINP"). The study met its prespecified primary endpoint, demonstrating a statistically significant increase in the proportion of patients achieving at least a 50% reduction from baseline in weekly average pain intensity at Week 4 as compared with placebo. The observed 50% pain reduction represents a treatment effect that is clinically meaningful in this difficult-to-treat condition for which there are no FDA-approved treatments. Notably, reduction in pain was observed when Halneuron® was used alone or when used on top of other approved chronic pain medications.

A total of 239 patients with moderate-to-severe CINP were randomized 1:1 to receive Halneuron® or placebo. Patients received eight subcutaneous injections of Halneuron® or placebo over a two-week treatment period, with the primary endpoint at Week 4. The study enrolled patients with neuropathic pain secondary to prior treatment with neurotoxic chemotherapy agents, including platinum-based compounds and taxanes. Enrolled patients had experienced CINP for a mean duration of approximately 5.6 years for Halneuron®-treated patients and 4.4 years for placebo-treated patients. Halneuron® was generally well tolerated, with an overall dropout rate of 4.2%. Most adverse events ("AEs") were mild to moderate in severity.

"We are thrilled with the groundbreaking results of this landmark study and look forward to advancing Halneuron® toward registration trials in CINP. The long-standing promise of Na_v 1.7 inhibition delivering significant pain reduction has now been validated in patients suffering from CINP, a very difficult to treat

illness for which there are no approved treatments," said Greg Duncan, Chief Executive Officer of Dogwood Therapeutics. "The pain reduction treatment benefits Halneuron® delivered, combined with what appears to be a best-in-class chronic pain medicine tolerability profile, suggest Halneuron® could represent the first new therapeutic agent for millions of CINP patients across the globe."

The treatment responder rates and the tolerability profile observed for Halneuron® in this trial represent a real breakthrough for CINP patients and suggest that selective Na_V 1.7 modulation has therapeutic relevance in treating multiple forms of neuropathic pain," said R. Michael Gendreau, M.D., Ph.D., Chief Medical Officer. "This study provides important clinical evidence validating the biological mechanism of Halneuron® and supports our planned Phase 3 development strategy in CINP and other neuropathic pain conditions."

Patient Demographics

PATIENT DEMOGRAPHICS	Halneuron® n=120	Placebo n=119
Age	65.4	64.9
% Female	83.3%	78.2%
Baseline Pain Score	6.1	6.0
On Any Background Concomitant Pain Medication	51.7%	57.1%
On duloxetine/TCAs	20.0%	21.8%
On gabapentinoids	39.2%	42.9%
On opioids	13.3%	10.9%
Years since CINP Onset	5.6	4.4
Platinum Chemotherapy Agent Induced CINP	38.3%	42.0%
Taxane Chemotherapy Agent Induced CINP	32.5%	34.4%
Both Platinum and Taxane	29.2%	23.5%

Halneuron® Phase 2b CINP Top-Line Results

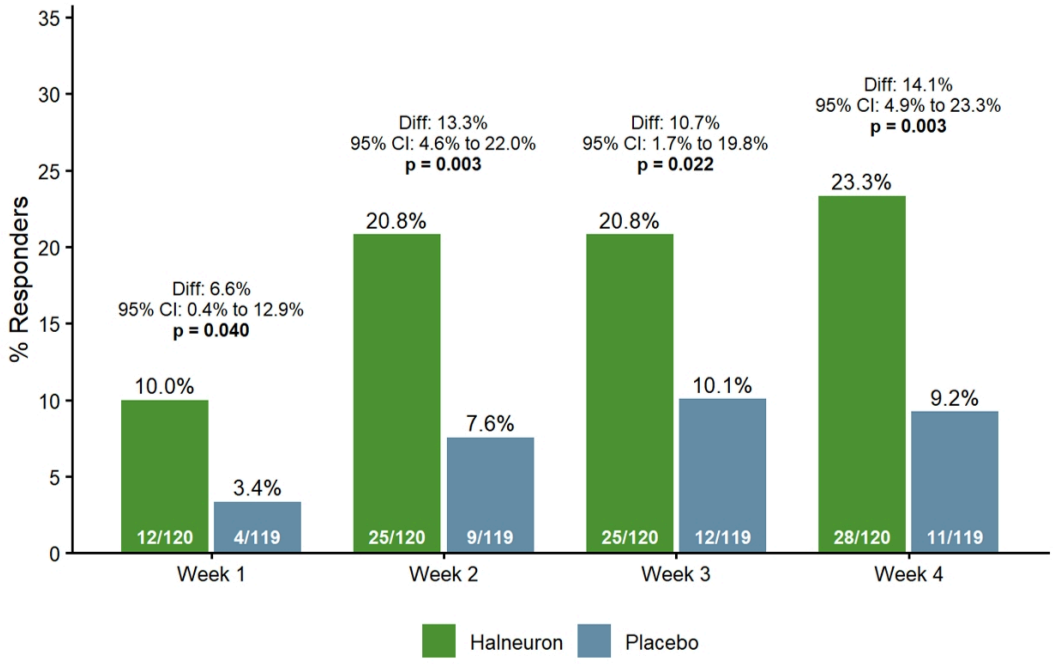
The prespecified primary endpoint was the proportion of patients completing the full study and achieving a 50% or greater reduction from baseline in the weekly average of daily 24-hour recall pain intensity scores, as measured by the 11-point Numeric Pain Rating Scale (NPRS), at Week 4.

Primary Endpoint Result

Endpoint	Halneuron® (n=120)	Placebo (n=119)	Treatment Difference	p-value
≥ 50% NPRS responder rate at Week 4	23.3%	9.2%	14.1%	p=0.003

- Key findings included:**23.3%** of patients receiving Halneuron® achieved at least a 50% reduction in pain intensity compared with **9.2%** of patients receiving placebo (**p=0.003)**.
- Halneuron® treatment demonstrated a statistically significant improvement versus placebo on the primary endpoint at every study week.

Proportion of Patients Who Achieved ≥ 50% Reduction from Baseline in Average Weekly Pain Intensity at Week 4



Other Key Study Results

- Halneuron® treatment demonstrated statistically significant improvement on key secondary global assessment endpoints:

- Neuropathic pain (p=0.027)
- Numbness and tingling (p=0.025)
- QoL measures (p=0.006)

- Halneuron® treatment demonstrated a statistically significant improvement of CINP patients' pain interference by 50% or greater with activities at work, leisure, or home over placebo (p=0.026).
- Halneuron® pain reduction was observed when used alone or on top of other chronic pain medications, including opioids, gabapentinoids and duloxetine/TCAs, for patients suffering from moderate-to-severe CINP.
- Halneuron® was generally well tolerated, with an adverse event related dropout rate of 2.5%, compared to placebo (1.7%).

Detailed analyses of secondary endpoints will be reported following completion of ongoing statistical review.

Safety and Tolerability

Halneuron® was generally well tolerated. More than **95%** of randomized participants completed the study.

Treatment-emergent adverse events ("TEAEs") were reported in **90.0%** of patients receiving Halneuron® and **54.6%** of patients receiving placebo and were generally mild to moderate in severity.

The most frequently reported treatment-emergent adverse events were:

TEAE Preferred Term	Halneuron® (N=120)	Placebo (N=119)
Paraesthesia oral (lips, tongue, mouth tingling)	70.0%	7.6%
Hypoesthesia oral (numbness in oral cavity)	35.0%	1.7%
Paraesthesia	23.3%	8.4%
Headache	15.8%	9.2%
Nausea	15.0%	6.7%
Hypoesthesia	11.7%	2.5%
Fatigue	9.2%	1.7%
Dizziness	8.3%	3.4%
Blood pressure increased	6.7%	0.8%
Dysgeusia (taste distortion)	6.7%	1.7%
Somnolence	5.8%	0.8%

Most adverse events were mild to moderate in severity.

Discontinuations due to adverse events occurred in **2.5%** and **1.7%** of patients in the Halneuron® and placebo groups, respectively.

The safety profile observed in the Phase 2b study was generally consistent with that reported in previous clinical studies of Halneuron®.

About the Phase 2b Study

The Phase 2b study was a multicenter, randomized, double-blind, placebo-controlled clinical trial conducted at 27 sites in the United States evaluating Halneuron® in patients with chemotherapy-induced neuropathic pain.

Key Study Characteristics

- Enrollment: 239 patients
- Randomization: 1:1
- Study duration: 4 weeks
- Primary endpoint: Proportion of patients achieving ≥ 50% reduction in weekly average pain intensity at Week 4
- Assessment tool: 11-point Numeric Pain Rating Scale (NPRS)
- Mean CINP duration of 5.6 years for Halneuron®-treated patients and 4.4 years for placebo-treated patients.
- Mean baseline NPRS score: 6.1 for Halneuron® and 6.0 for placebo

About Chemotherapy-Induced Neuropathic Pain (CINP)

Chemotherapy-induced neuropathic pain is a chronic and potentially debilitating complication of cancer treatment resulting from damage to peripheral nerves caused by neurotoxic chemotherapy agents. Symptoms may include pain, numbness, tingling, burning sensations, and impaired physical function. CINP can persist long after completion of chemotherapy and may substantially affect quality of life and daily functioning. There are currently no FDA-approved therapies specifically indicated for the treatment of CINP.

Conference Call and Webcast

The Company will host a webcast presentation to discuss the top-line results today, November 23, 2026 at 8:30 a.m. Eastern Time.

Registration Details

Toll Free: 1-877-407-0784

International: 1-201-689-8560

Participant Access Code: 13763933

CallMe™: Click here

Webcast: Click here

A replay of the webcast will also be available via the investor website after the call's conclusion.

About Halneuron®

Halneuron® is an investigational, selective modulator of the Na_V 1.7 sodium channel being evaluated for the treatment of neuropathic pain conditions. Halneuron® has not been approved by the FDA or any other regulatory authority. Na_V 1.7 has been identified as a key regulator of pain signaling pathways, and the Company believes it is a promising biological target for pain modulation.

About Dogwood Therapeutics

Dogwood Therapeutics (Nasdaq: DWTX) is a development-stage biopharmaceutical company focused on developing potential first-in-class, non-opioid medicines to treat pain and neuropathic disorders. Dogwood's research pipeline includes two potential first-in-class development candidates, Halneuron® and SP16 IV.

Our lead product candidate Halneuron® is a non-opioid, Na_V 1.7 analgesic which is a highly specific voltage-gated sodium channel modulator, a mechanism known to be effective for reducing pain transmission. Halneuron® delivered clinically significant pain reduction of 50% or greater as compared with a placebo in a recently completed Phase 2b CINP study (n=239) of patients with a mean five-year duration of illness. Halneuron® has been granted Fast Track Designation from the FDA for the treatment of CINP. Halneuron® treatment has also demonstrated pain reduction related to general cancer pain, including both neuropathic and non-neuropathic pain, as well as patients not treated with chemotherapy.

SP16 IV is a low-density lipoprotein receptor related protein-1 agonist ("LRP1") with potential to treat neuropathy and prevent or repair nerve damage following chemotherapy. SP16 acts as an LRP1 agonist that in turn provides alpha-1-antitrypsin-like activity. Consistent with alpha-1-antitrypsin anti-inflammatory and immunomodulatory actions, SP16 preclinically demonstrated anti-inflammatory (analgesic) action via potential reductions in IL-6, IL-8, IL1B and TNF-alpha levels, as well as potential to repair damaged tissue via increases in pAKT and pERK that regulate fundamental processes like growth, proliferation and survival. The forthcoming SP16 IV Phase 1b CIPN trial is fully funded by the National Cancer Institute.

Dogwood Therapeutics' largest shareholder is a member of CK Life Sciences Int'l., (Holdings) Inc., which is listed on the Hong Kong Stock Exchange (Stock code: 0775).

For more information, please visit www.dwtx.com.

Forward-Looking Statements:

Statements in this press release contain "forward-looking statements," within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All

statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “suggest,” “target,” “aim,” “should,” "will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on Dogwood’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing, enrollment, design and results of future clinical studies relating to Dogwood’s product candidates; whether interim or final clinical data will support continued development, regulatory submissions or approval; and Dogwood’s ability to finance its operations. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the most recently filed Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Dogwood undertakes no duty to update such information except as required under applicable law.

Investor Relations:

Dan Ferry
Managing Director
LifeSci Advisors, LLC
daniel@lifesciadvisors.com

Exhibit 99.2

DOGWOOD THERAPEUTICS

Halneuron® for the Treatment of Chronic Neuropathic Pain

November 2026

NASDAQ: DWTX

Forward-Looking Statements

Statements in this presentation contain “forward-looking statements,” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this presentation are forward-looking statements. Forward-looking statements contained in this presentation may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “suggest,” “target,” “aim,” “should,” "will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on the current expectations of Dogwood Therapeutics, Inc. (“Dogwood”) and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of future clinical studies relating to Dogwood’s product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission. Forward-looking statements contained in this presentation are made as of this date, and Dogwood undertakes no duty to update such information except as required under applicable law.

Therapeutic Pain and Neuropathy Pipeline

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	2026 Milestones
Halneuron® Injection	**Chemotherapy Induced Neuropathic Pain (CINP)** Fast Track Designation					Q4'26 EOP2 FDA Submission Applying for Breakthrough Status based on statistically significant outcomes in an indication with no approved therapy
	General Cancer Pain					Completed P2 Study Demonstrated Statistically Significant Pain Reduction
SP16 IV	**CIPPN** NCI Funded					IND Accepted by FDA P1b Commences Enrollment Q1 2027

Chemotherapy induced neuropathic pain (CINP), Chemotherapy Induced Neuropathic Peripheral Neuropathy (CIPPN)

Executive Team

Experienced Leadership



Greg Duncan
Chairman & CEO



R. Michael Gendreau MD, PhD
Chief Medical Officer



Angela Walsh
Chief Financial Officer



Ralph Grosswald
Senior VP, Operations



Scott Millard
VP, Research



Jerry Evarts
VP, Manufacturing

Proven Record of Drug Development & Commercial Success

The Problem: CINP Patient Journey



Chemotherapy Induced Neuropathy Symptom Onset

Patients Experience

- Pain
- Numbness
- Tingling
- Sensitivity to cold
- Muscle weakness
- Balance disturbance, and others

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Oncologist Pain Related Cancer Treatment Considerations

- Mild Pain – continue chemo + monitor
- **Moderate Pain** – dose reduction/delay
- **Severe Pain** – discontinue chemo

Goal: Maximize Chemo Regimen Effectiveness

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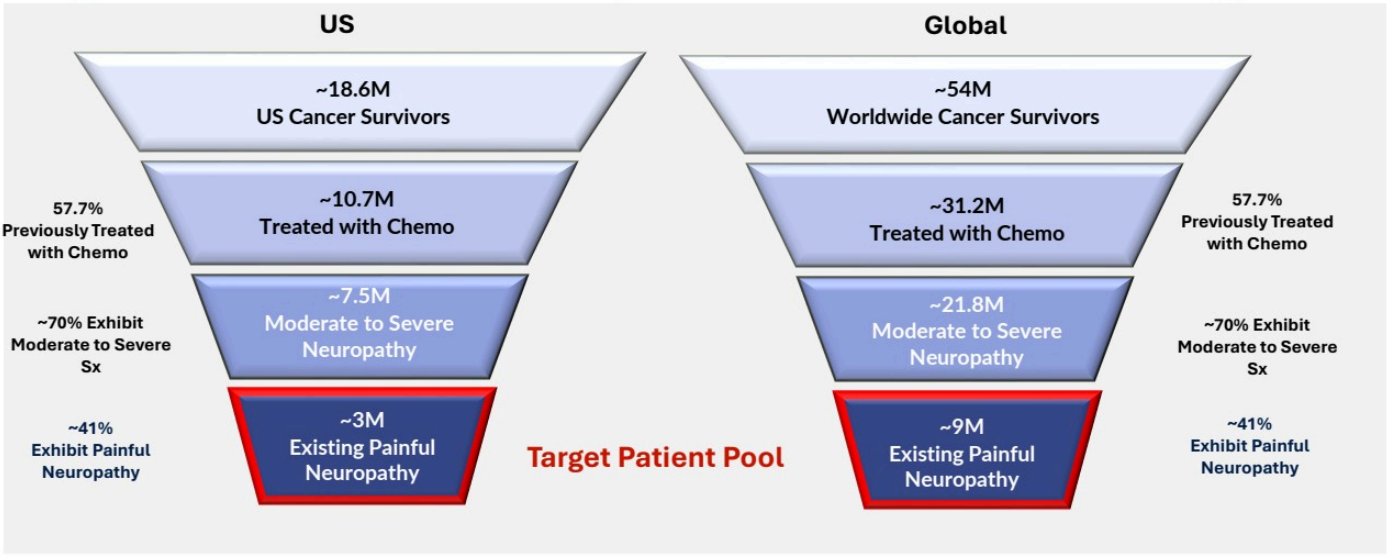
Pain Specialists Initial Commercial CINP Call Point

- Post chemo, patients referred to pain centers
- **Pain specialist (i.e. neurologists, anesthesiologists, etc.)**

Goal: Reduce Chronic Pain, Numbness, Tingling

Existing Moderate-to-Severe CINP Patients Represent a Major Unmet Medical Need, Both in the US and Globally



Worldwide incidence of cancer is projected to grow by 53% by 2040

DOGWOOD THERAPEUTICS

Sources: ACS Cancer Facts & Figures 2025; Sreeram 2023; D'Souza 2025; BMJ, 2026; Anderer 2025; JAMA

Projected US and Global Annual Increase in Moderate-to-Severe CINP Patient Pool

US Annual Estimated Burden of New Cancers

Cancer Type	New Cases
Genital System	444,610
Digestive System	362,200
Breast	319,750
Respiratory	245,700
Urinary	170,470
Skin	112,690
Lymphoma	89,070
Leukemia	66,890
Oral & Pharynx	59,660
Endocrine	52,140
Other	44,280
Myeloma	36,110
Brain & Other Nervous	24,820
Soft Tissue	13,520
Total New	2,041,910

2,041,910

57.7%
Treated of Cancer Patients Treated with Chemo

1,178,182

~70%
Exhibit/Developing Moderate-to-Severe Neuropathy

824,727

~41%
Exhibit Painful Neuropathy

~340K Patients

New US Moderate/Severe CINP Patients/Annum

Global Annual Estimated Burden of CINP

~20M New Cancer Cases Globally

~11.5M CIPN Patients 3 Months Post Chemotherapy

~8.1M Moderate - Severe New Cases Annually

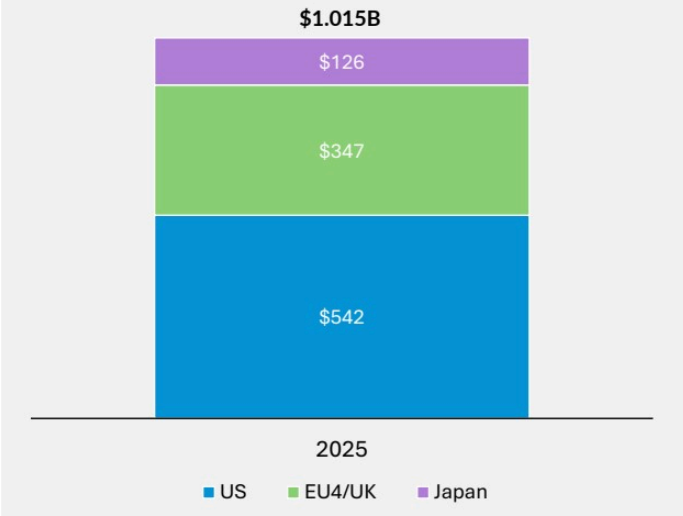
~3.3M Painful CIPN New Cases Annually

DOGWOOD THERAPEUTICS

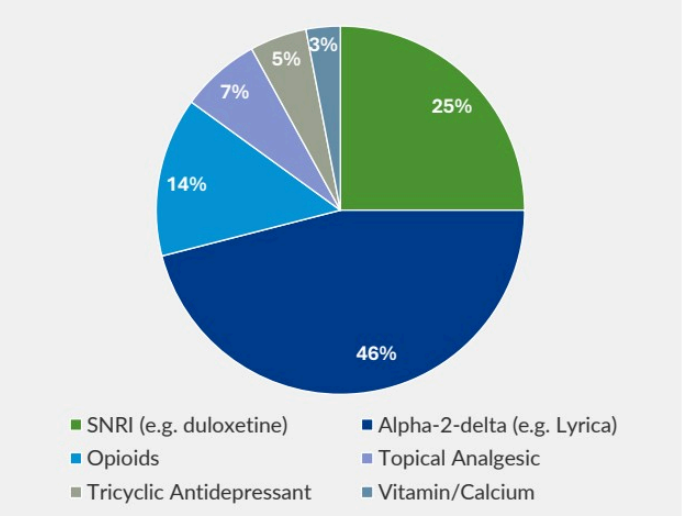
Sources: ACS Cancer Facts & Figures 2025; Sreeram 2023; D'Souza 2025; BMJ 2026

Significant CINP Treatment Market Across 7 Major Markets (7MM), Despite No FDA Approved Treatments

Total Market Sales ($M)



Market Share (%) by Therapy in the 7MM, 2026



DOGWOOD THERAPEUTICS

Source: Delve Insight, 2025

Halneuron® Background

Our Solution Halneuron®

Halneuron® is Tetrodotoxin (TTX), a voltage-gated sodium channel blocker and potent small molecule found in puffer fish and several other marine animals (not a peptide or protein)

- Prevents or relieves pain by interrupting nerve conduction
- Modulates pain transmission in the peripheral nerves, no CNS effects
- Administered as a sub-Q injection
- Halneuron® treatment has demonstrated statistically significant, durable pain reduction, with acceptable safety profile, in cancer and chemotherapy related clinical pain studies to date
- New synthetic TTX manufacturing patents, if granted, enable intellectual property protection to 2046



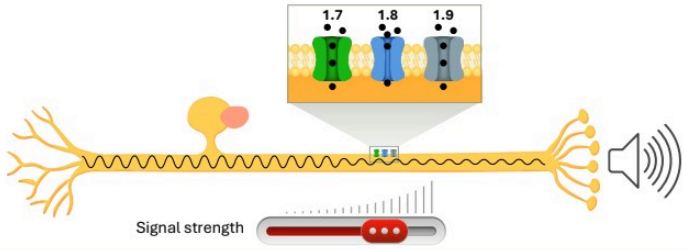
How Does Halneuron® Work?

- Halneuron® works as an analgesic by binding to the Nav1.7, channel, a sodium channel responsible for pain signal transmission
- Genetic Loss of NA_V 1.7 Function Leads to Congenital Insensitivity to Pain Syndrome



Na_v Sodium Channel Signaling

Nerve Damage from Chemotherapy Triggers Pain Signaling



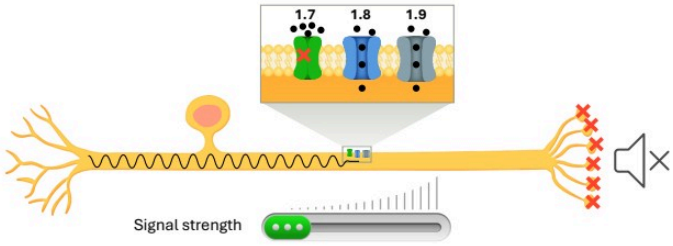
The Role of Na_v Sodium Channels

Na_v 1.7
Critical to setting the depolarization threshold, and therefore the probability of triggering an electrical signal required to transmit pain signals ("on/off switch")

Na_v 1.8
Acts as a "dimmer or amplifier " thought to increase pain signaling duration or intensity

Na_v 1.9
Thought to be involved in cold pain sensing and small fiber neuropathy.

Halneuron Na_v1.7 Inhibition



What makes Halneuron® different?

- Selectively inhibits Na_v 1.7 sodium channel signaling rather than Na_v 1.8
- Preclinical data demonstrates:
  - Pain reduction > Na_v 1.8 inhibitor in preclinical rat model
  - No additional pain reduction effect when combining a Na_v 1.8 inhibitor with Halneuron®, highlighting importance of the Na_v 1.7 target

Halneuron® (TTx) Sensitivity to Sodium Channel Isoforms

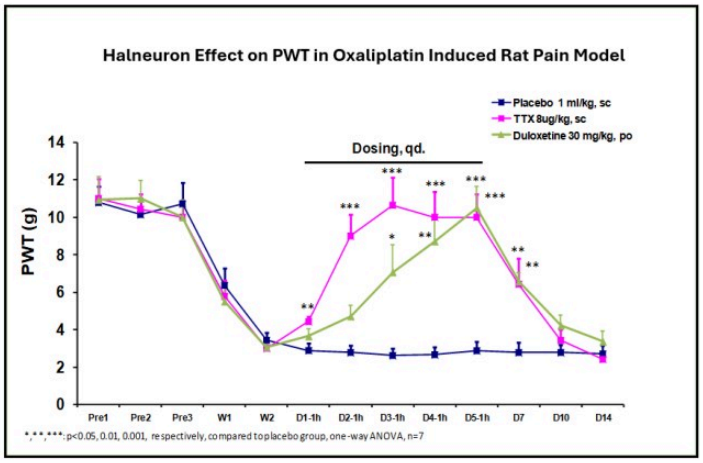
Channel	TTX Sensitivity	Predominant Distribution
$Na_v1.7$	**EC_{50} = 24.5 nM**	**PNS (DRG)**
$Na_v1.8$	EC_{50} = 60,000 nM	PNS (DRG)
$Na_v1.9$	EC_{50} = 40,000 nM	PNS (DRG)
$Na_v1.4$	EC_{50} = 25 nM	Skeletal Muscle
$Na_v1.5$	EC_{50} = 5,700 nM	Heart
$Na_v1.1$	EC_{50} = 6 nM	CNS
$Na_v1.2$	EC_{50} = 18 nM	CNS
$Na_v1.3$	EC_{50} = 4 nM	CNS
$Na_v1.6$	EC_{50} = 6 nM	CNS

- TTX preferentially acts to block pain signals through $Na_v1.7$
- TTX unable to cross the blood-brain barrier
- Relief of chronic pain without the common CNS side effects

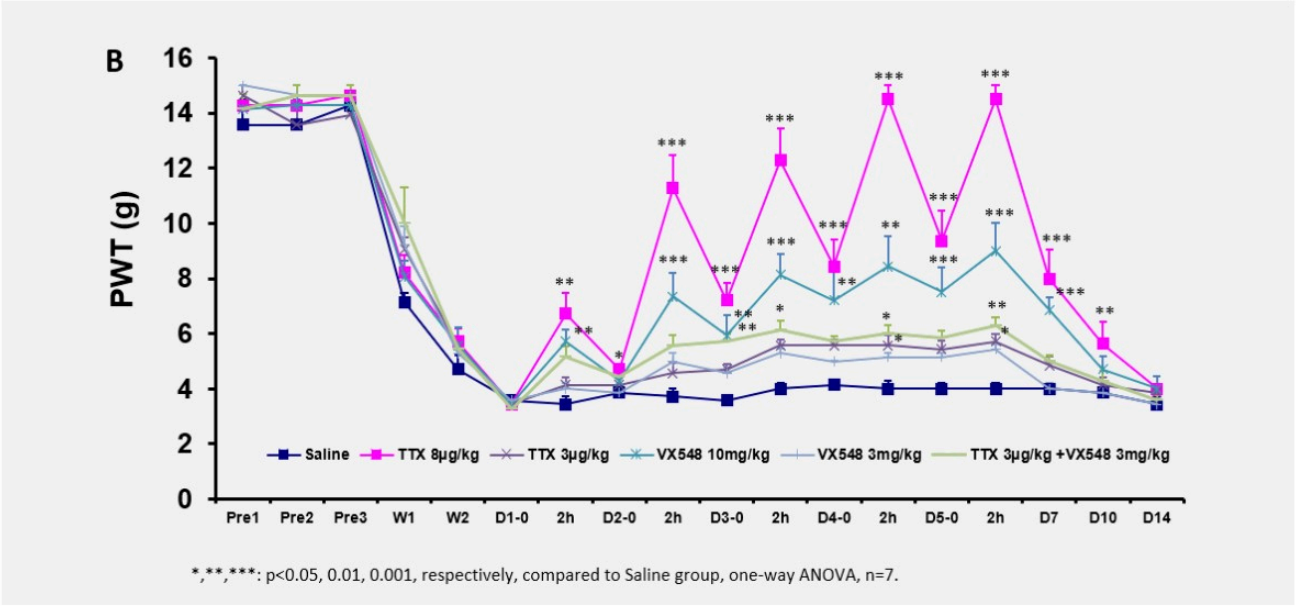
Channels 2(6): 407-412, 2008. Lee et al.

Halneuron® Demonstrated Pain Reduction in Preclinical Chemotherapeutic-Induced Rat Pain Model

- Adult male Sprague-Dawley rats.
- Oxaliplatin 4 mg/kg, injected intravenously, twice a week, repeated up to 9 times.
- Paw withdrawal threshold (PWT)
- The rats showing significant mechanical allodynia
  - (PWT ≤ 4g) were used.
- TTX/vehicle injected subcutaneously, q.d.
- Duloxetine given orally, at 30 mg/kg, q.d.as active control



Halneuron® Pain Reduction in Preclinical Paw Withdrawal Model > VX548 at all High, Medium and Low Doses



*,**,***: p<0.05, 0.01, 0.001, respectively, compared to Saline group, one-way ANOVA, n=7.

Halneuron® Phase 2b Study

Halneuron® Phase 2b Study Highlights

P value = 0.003
Primary endpoint met
≥50% pain reduction at Week 4

~2.5x
Responder rate vs. placebo
(23.3% vs. 9.2%)

~9M
Global survivors with painful CINP (~3M US)

~$1.0B
Current CINP market
No FDA-approved therapy

High-Quality, Consistent Halneuron® Phase 2b Data

1. **Primary endpoint met with robust significance**
   23.3% vs. 9.2% of patients achieved ≥50% pain reduction at Week 4 (p=0.003); statistically significant at every weekly visit beginning at Week 1 (p=0.04)

2. **Consistent across secondary and sensitivity analyses**
   Demonstrated statistical significance on primary responder analysis at every visit and on PGIC: Quality of Life (p=0.006), Neuropathic Pain (p=0.027), Numbness and Tingling (p=0.025)

3. **Well tolerated with durable benefit**
   95.8% study completion in both arms; AEs predominantly mild and mechanism-related; ~50% response in 12-week OLE; 57.7-day mean response duration in prior Phase 2 cancer pain study

Large, Underserved Market Opportunity

4. **Large and growing patient population**
   ~9 million cancer survivors suffer from CINP today, with ~3.3M new CINP cases each year

5. **~$1.0B spent today on inadequate off-label options**
   Alpha-2-delta agents (46%), SNRIs (25%) and opioids (14%) lead 7MM share despite CNS and addiction liabilities; no FDA-approved CINP therapy

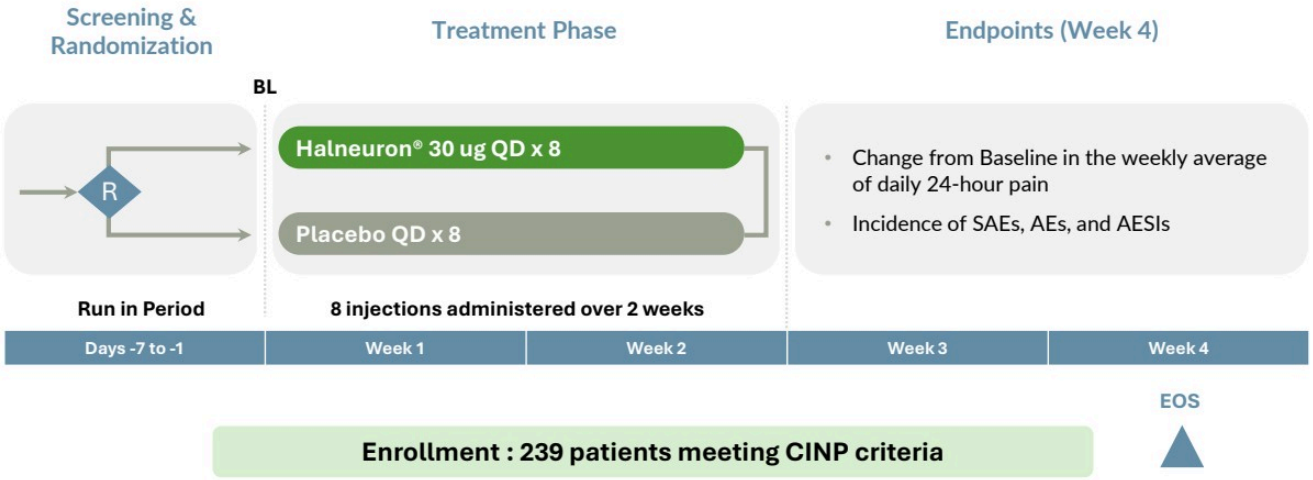
6. **Differentiated, late-stage and protected asset**
   Peripherally acting NaV1.7 blocker with no CNS effects; most advanced NaV1.7 program (next-closest in Phase 1); New Halneuron® synthetic manufacturing process enables IP protection, if granted, to 2046

DOGWOOD THERAPEUTICS

Sources: HAL-CINP-203 Phase 2b topline data; Delve Insight 2025; ACS Cancer Facts & Figures 2025. 7MM = 7 major markets; AE = adverse event; CNS = central nervous system; OLE = open-label extension; PGIC = Patient Global Impression of Change; SNRI = serotonin-norepinephrine reuptake inhibitor.

Halneuron® 4-Week Phase 2b (HAL-CINP-203) Study Design

Primary Objective was to explore the safety and efficacy of Halneuron® in the treatment of patients with moderate-to-severe CINP



Enrollment : 239 patients meeting CINP criteria

HAL-CINP-203: Disposition

Disposition	Halneuron®	Placebo	Total
Randomized	120	119	239
Completed	115 (95.8%)	114 (95.8%)	229 (95.8%)
Discontinued Early	5 (4.2%)	5 (4.2%)	10 (4.2%)
Discontinued Study due to AE	3 (2.5%)	2 (1.7%)	5 (2.1%)

Only **5 (2.1%)** of the patients who completed the study did not receive all 8 injections

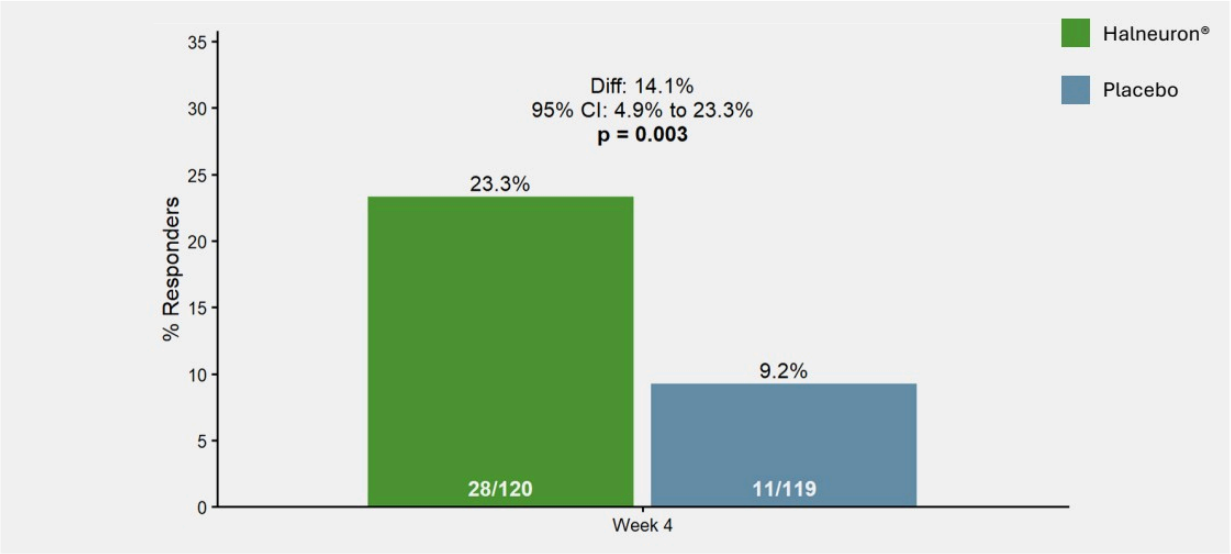
HAL-CINP-203: Baseline Characteristics

Characteristic	Halneuron® (N=120)	Placebo (N=119)
Age	65.4	64.9
% Female	83.3%	78.2%
Baseline Pain Score	6.1	6.0
On Any Concomitant Pain Medication	51.7%	57.1%
Duloxetine/TCAs	20.0%	21.8%
Gabapentinoids	39.2%	42.9%
Opioids	13.3%	10.9%
Years since CINP Onset	5.6	4.4
Prior Platinum Use	38.3%	42.0%
Prior Taxane Use	32.5%	34.4%
Prior Platinum and Taxane Use	29.2%	23.5%

Cancer Hx
49% Breast
26% Colorectal
6% Ovarian
5% Pancreas
4% Lung
10% Other

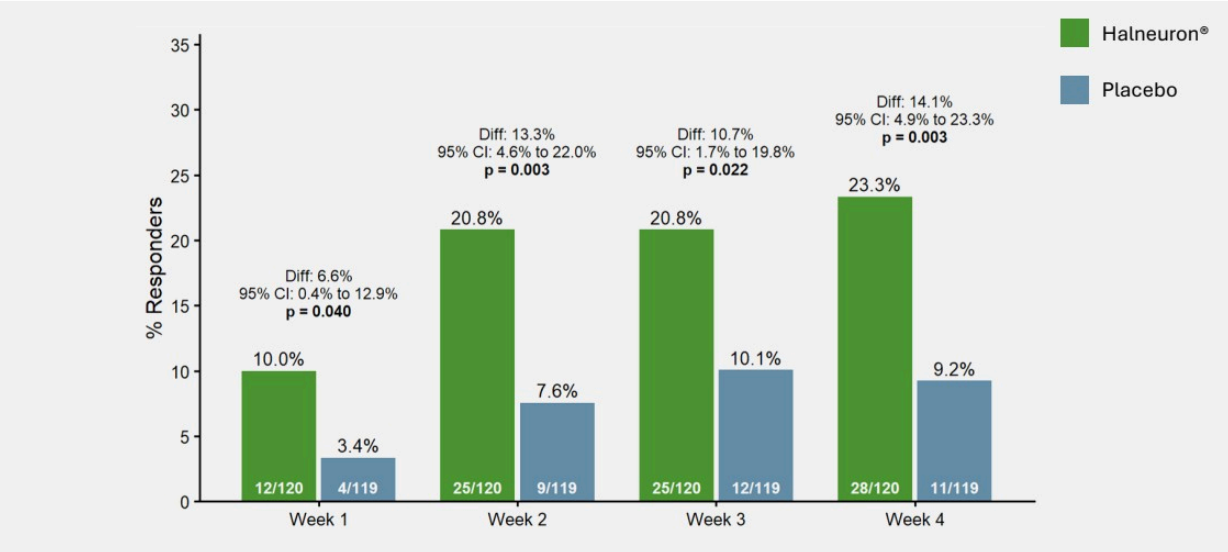
Primary Endpoint: 50% Responder Analysis for Pain Intensity

Proportion of Patients who achieved ≥50% Reduction at Week 4 from Baseline in Average Weekly Pain Intensity



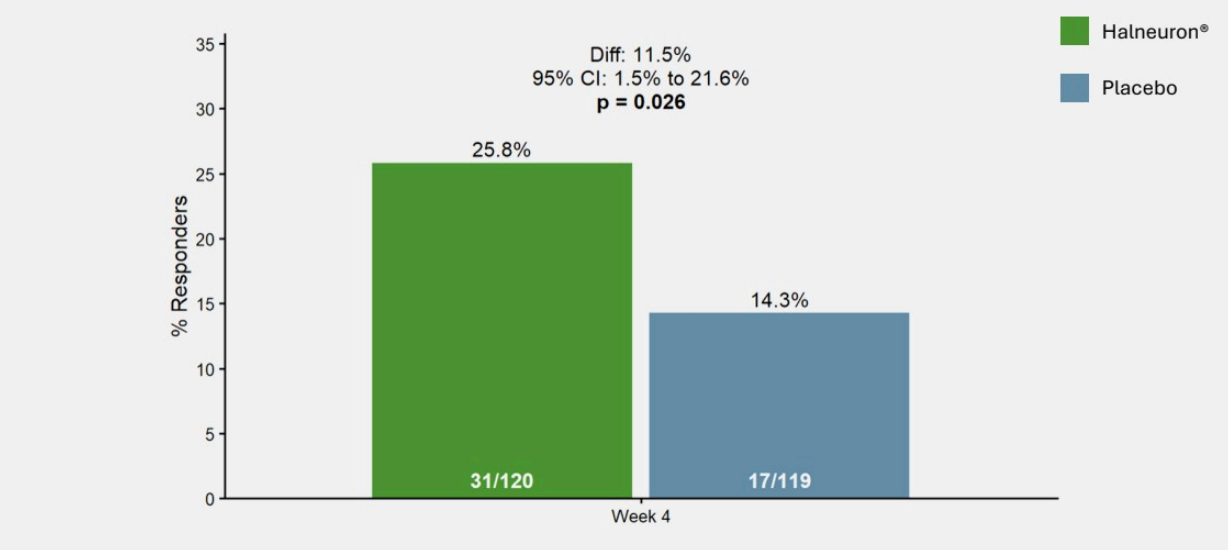
Primary Endpoint: 50% Responder Analysis By Week

Proportion of Patients who achieved ≥50% Reduction from Baseline in Average Weekly Pain Intensity



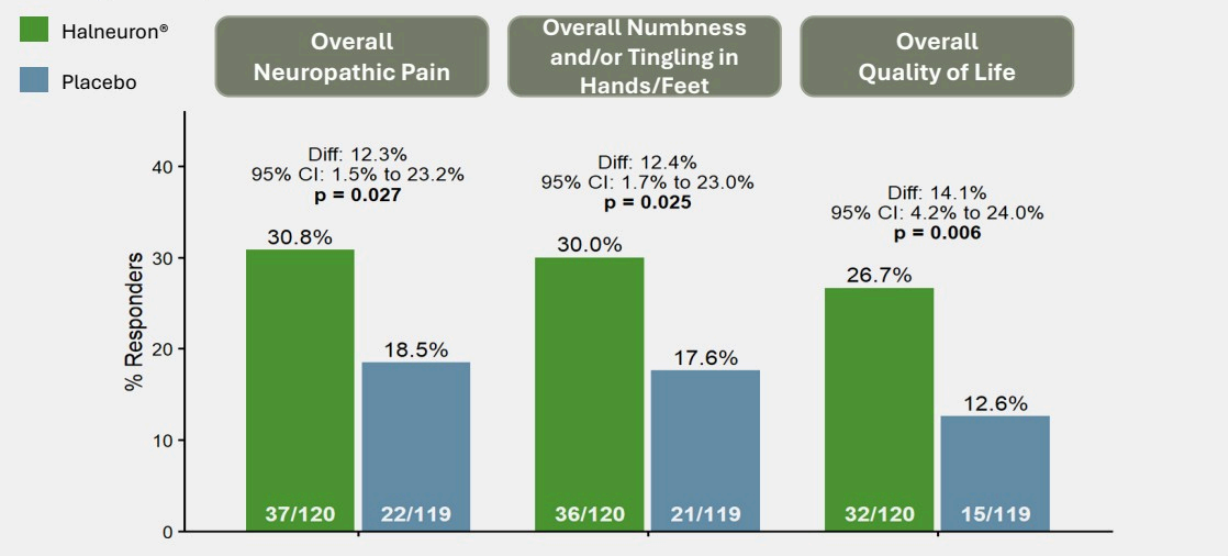
50% Responders: Pain Interference

Proportion of Patients who Achieved ≥50% Reduction from Baseline in Average Weekly Pain Interference at Week 4



PGIC Responder Analysis (Very Much or Much Improved)

Secondary Endpoint



1 Very Much Improved	2 Much Improved	3 Minimally Improved	4 No Change	5 Minimally Worse	6 Much Worse	7 Very Much Worse

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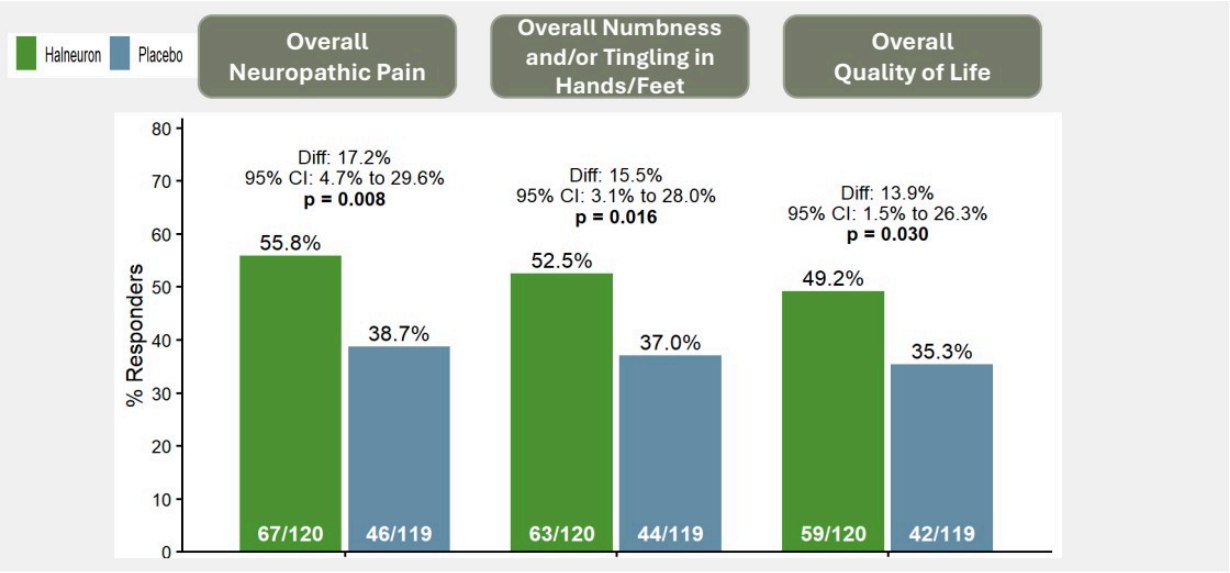
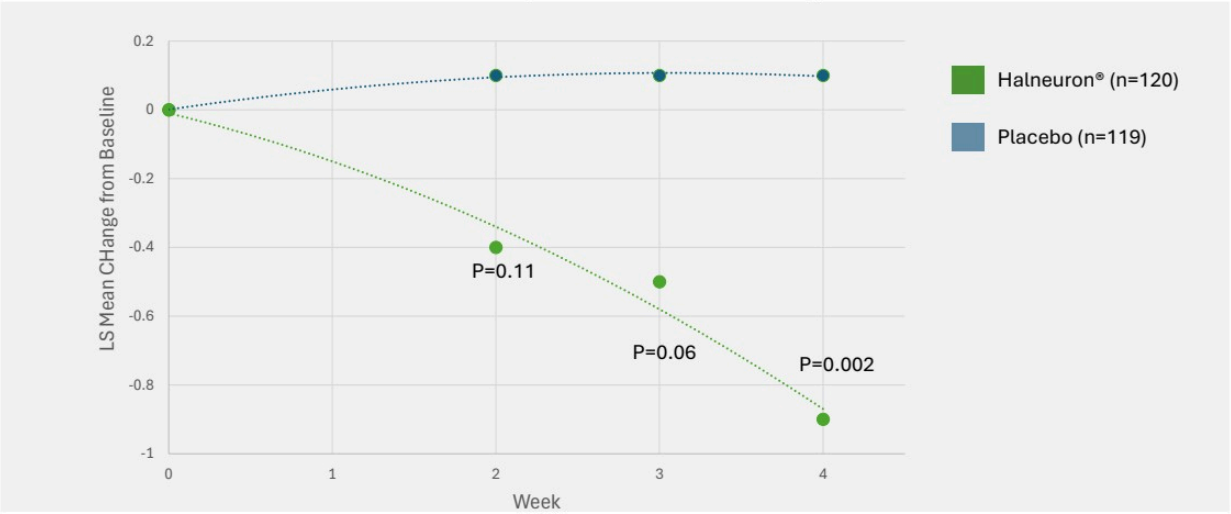
PGIC Responder Analysis (Any Improvement)

Secondary Endpoint



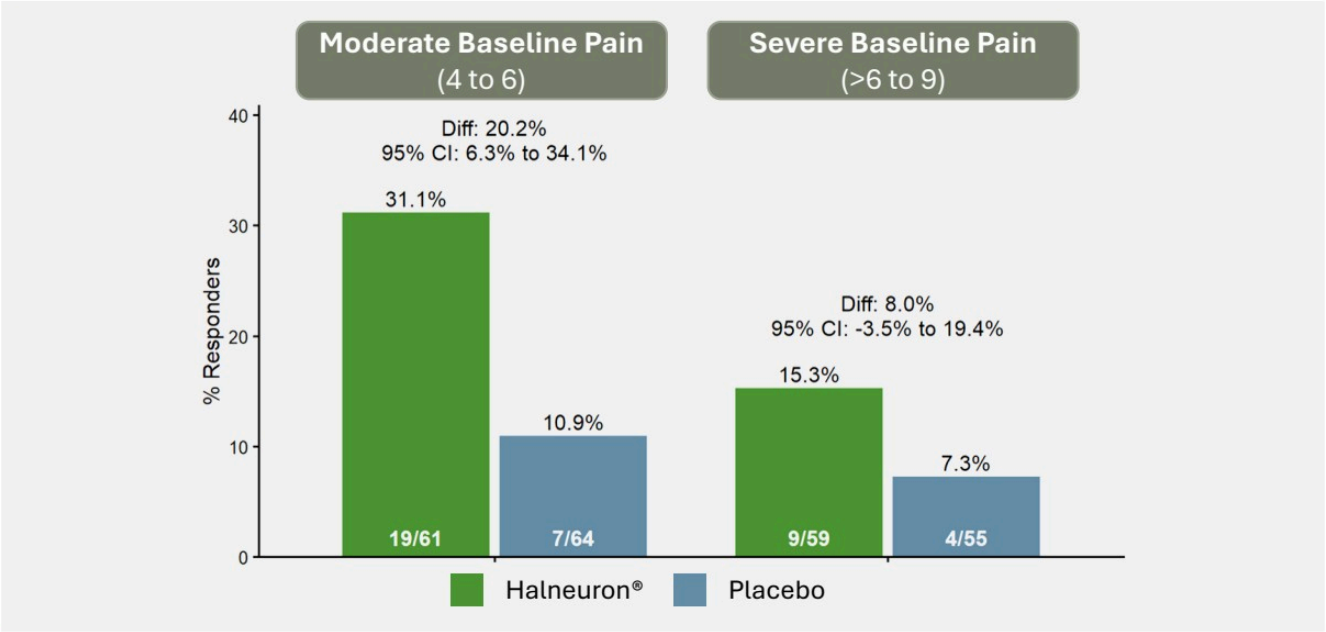
Halneuron® Treatment Improved CINP Patient Depression

Comparison of Group Mean Change from Baseline in the Hospital Anxiety & Depression Score BY MMRM (Baseline Scores 4.9 vs 4.8)



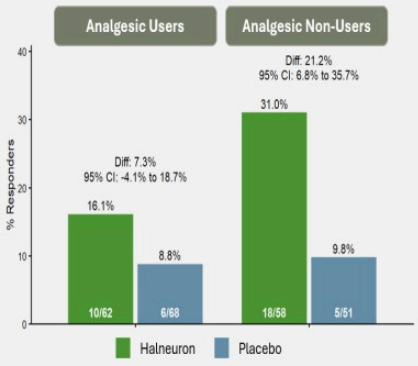
Subset Analysis of Primary Endpoint

By Baseline Pain Score

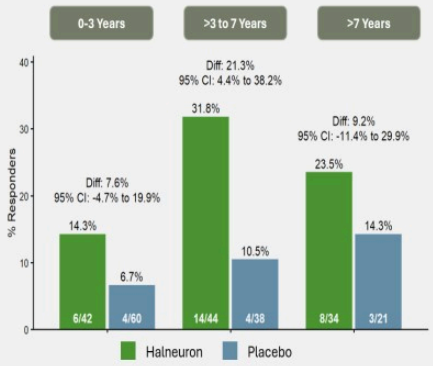


Subset Analysis of Primary Endpoint

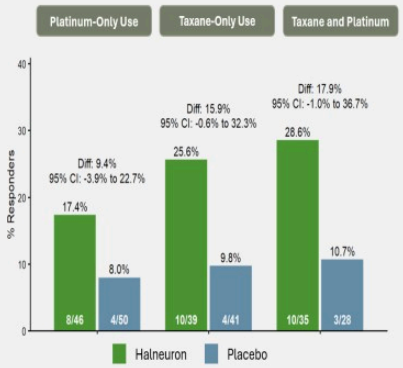
By Concomitant Analgesic Medication Usage



By CINP Duration



By Chemotherapy Type



Treatment-Emergent Adverse Events

≥5% with Halneuron® and Higher than Placebo

TEAE Preferred Term	Halneuron® (N=120)	Placebo (N=119)
Paraesthesia oral (lips, tongue, mouth tingling)	70.0%	7.6%
Hypoesthesia oral (numbness in oral cavity)	35.0%	1.7%
Paraesthesia	23.3%	8.4%
Headache	15.8%	9.2%
Nausea	15.0%	6.7%
Hypoesthesia	11.7%	2.5%
Fatigue	9.2%	1.7%
Dizziness	8.3%	3.4%
Blood pressure increased	6.7%	0.8%
Dysgeusia (taste distortion)	6.7%	1.7%
Somnolence	5.8%	0.8%

Details on Paraesthesias and Hypoesthesias in Halneuron® Group

Event type	% Halneuron® Participants with Event	Severity			Duration in Hours Median (IQR)
		Mild	Moderate	Severe	
Paraesthesia oral	70.0%	99.6%	0.4%	0%	2.3 (1.2 to 3.8)
Hypoesthesia oral	35.0%	99.0%	1.0%	0%	2.2 (1.2 to 3.6)
Paraesthesia	23.3%	99.5%	0.5%	0%	2.2 (0.9 to 4.0)
Hypoesthesia	11.7%	100%	0%	0%	3.2 (2.1 to 4.7)

Details Two SAEs

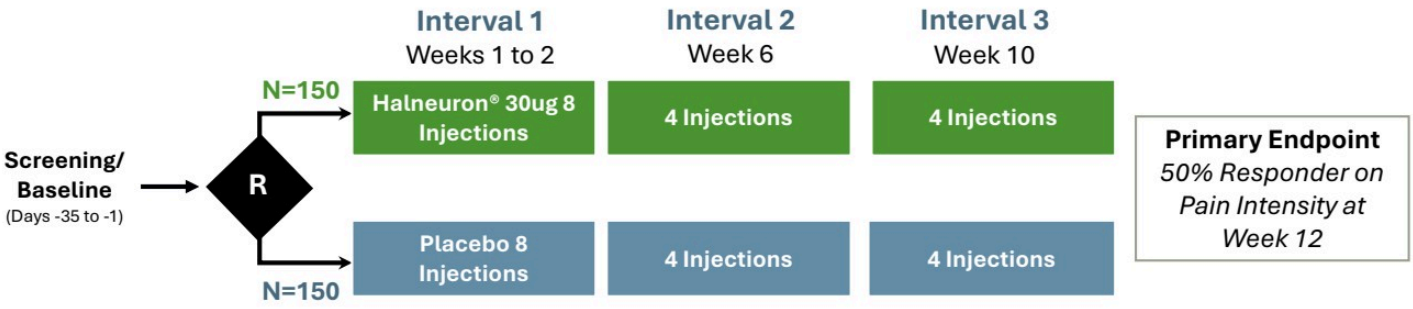
- **Two SAEs**
  - 102-002 78 year-old female; AE verbatim term: Syncope
    - SAE occurred 12 days after last injection while patient at physical therapy
    - Moderate, unlikely related (according to investigator); history of hypertension & severe valvular heart disease; Recovered same day
  - 110-001 48 year-old female; AE verbatim term: Rapid heart rate
    - Occurred at Visit 8 while patient in office for injection #8 (which was skipped due to SAE). No issues with previous 7 injections; patient continued in study and completed
    - Moderate; possibly related (according to investigator); however, history of supraventricular tachycardia (SVT) and paroxysmal SVT since 2021. SAE resolved by next day

Consistently Achieved Statistical Significance Across Multiple Endpoints, with Favorable Tolerability

Endpoint at Week 4	2-sided p-value
≥50% responder on pain intensity	0.003
≥50% responder on pain interference	0.026
≥30% responder on pain intensity	0.064
≥30% responder on pain interference	0.028
LS mean change from baseline in pain intensity (MMRM)	0.059
LS mean change from baseline in pain interference (MMRM)	0.040
PGIC (much or very much improved)	
Neuropathic pain	0.027
Numbness or tingling	0.025
Quality of life	0.006
PGIC (any improvement)	
Neuropathic pain	0.008
Numbness or tingling	0.016
Quality of life	0.030
Halneuron® overall discontinuation rate	**4.2%**
Halneuron® completers discontinuation rate due to AE	**2.5%**

Proposed Design for Halneuron® 30ug Phase 3 Studies

Two 12-Week, Randomized, Placebo-Controlled Trial



Assumptions

- Consistent with 12-week Special Protocol Assessment previously agreed upon with FDA
- Sample size based on treatment effect sizes from Phase 2b
- Interim analysis with 50% of participants evaluable
- Conducted exclusively in the US

Next Steps: Projected Path to Halneuron® 30ug Phase 3 & NDA

Key Next Steps

1. **FDA End-of-Phase 2 meetings:** confirm Week 12 ≥50% responder endpoint, Phase 3 design (consistent with prior SPA) and CMC / PK bridging plan
2. **Initiate US Phase 3 Study 1 (Q3'27):** interim analysis expected 2028
3. **Initiate US Phase 3 Study 2 (Q2'28):** potentially not required if FDA accepts a single pivotal study
4. **NDA submission:** targeted for 2030
5. **Breakthrough submission:** targeted Q1'27

Note: Timeline is a company projection. CMC = chemistry, manufacturing and controls; PK = pharmacokinetic bridging study; SPA = Special Protocol Assessment.

Key Takeaways: Halneuron® Phase 2b Top-Line Results

1. **Primary endpoint met, with clear separation from placebo**
   23.3% of Halneuron patients vs 9.2% on placebo achieved a ≥50% reduction in pain intensity at Week 4 (14.1-point difference; 95% CI 4.9–23.3; p=0.003), with separation from placebo at every weekly assessment (p≤0.04).

2. **Pain relief translated into improved daily function**
   ≥50% pain-interference responders 25.8% vs 14.3% (p=0.026); ≥30% responders 37.5% vs 24.4% (p=0.028); MMRM mean change favored Halneuron (p=0.04). Pain-intensity MMRM and ≥30% responder trended the same direction (p=0.059, 0.064).

3. **Patients reported feeling better across all three PGIC domains**
   Significant improvement: quality of life 26.7% vs 12.6% (p=0.006), neuropathic pain 30.8% vs 18.5% (p=0.027), numbness/tingling 30.0% vs 17.6% (p=0.025). Any improvement was also significant on all three domains (p=0.008–0.030).

4. **Effect was consistent regardless of analgesic use, CINP duration, or chemotherapy type**
   All 8 subgroups numerically favored Halneuron on the primary endpoint. Largest responses in analgesic non-users (31.0% vs 9.8%) and 3–7 years since onset (31.8% vs 10.5%); patients with CINP >7 years (23.5% vs 14.3%) and every chemotherapy type also favored Halneuron.

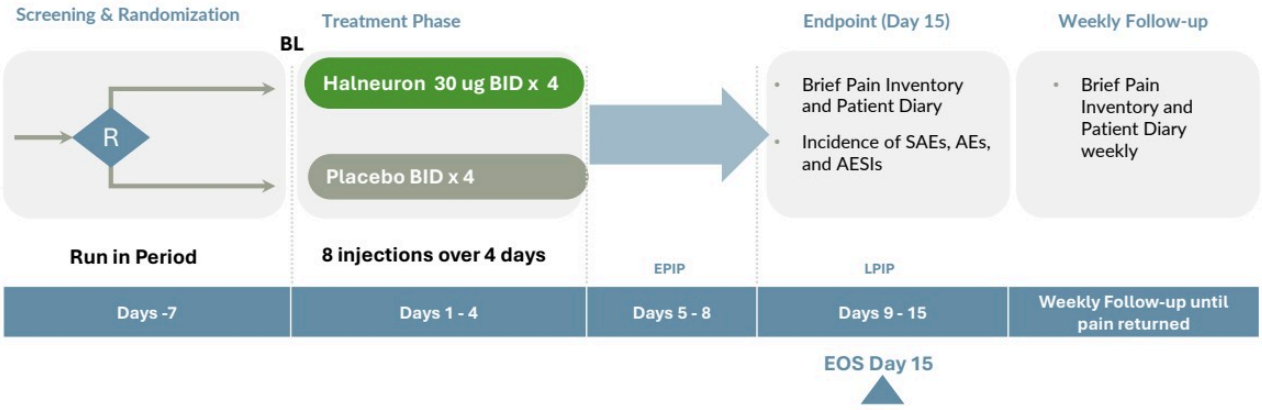
5. **Well tolerated: AEs were predominantly mild and transient**
   Discontinuation 4.2% overall and 2.5% due to AEs. Oral and peripheral paraesthesia / hypoesthesia were ≥99% mild with a median duration of 2–3 hours, and no severe events. Two SAEs (syncope; rapid heart rate), both in patients with pre-existing cardiac history, resolved within 24 hours.

6. **Data support Halneuron®'s potential as the first approved therapy for CINP**

Halneuron® Phase 2 Cancer Related Pain Study

CRP Phase 2 Study Design

All Comers with inadequately controlled moderate to severe cancer-related pain of at least two weeks' duration



Enrollment: 165 Cancer Patients

Halneuron® Demonstrated Statistically Significant Pain Reduction in Phase 2 Study

Compared

30 µg BID x 4 days

Placebo BID x 4 days

A "Responder" was defined as a patient who had a mean reduction in pain intensity of ≥ 30%; or ≥ 50% reduction in opioid use

Phase 2 Cancer Related Pain (n=165) – 8 Injections over 4 days – long term follow-up every 15 days after primary endpoint

	TTX		Placebo		Δ
Responder	33	51%	29	35%	16%
Non-Responder	32	49	55	65	
Total	**65**		**84**		
95% C.I.	0.4-32.1				
p-value	**0.046**				

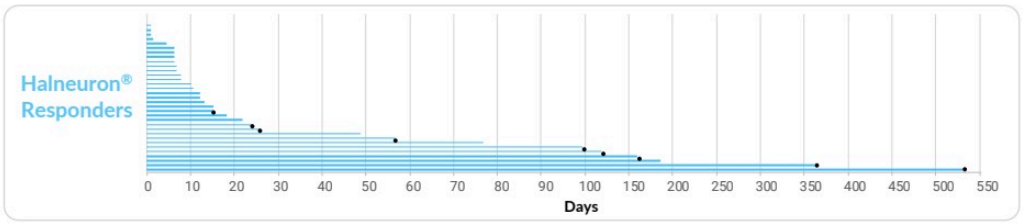
Conclusions

Halneuron® treatment demonstrated statistically significant reduction in cancer related pain

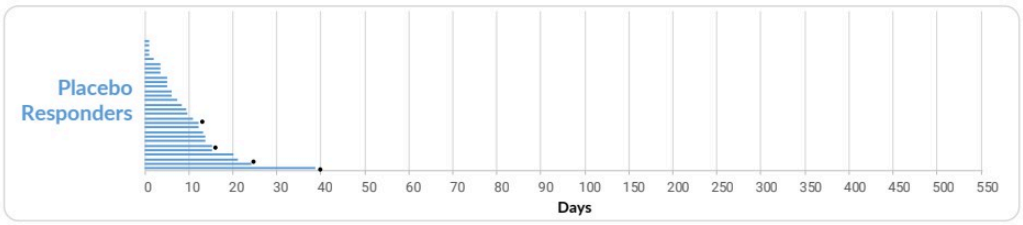
Halneuron® treatment reduced both neuropathic and non-neuropathic pain

Phase 2 CRP Study Demonstrated Durable Pain Relief in Initial Responders

Mean Pain Response For Halneuron® Responders Was 57.7 Days Vs 10.5 Days For Placebo Responders



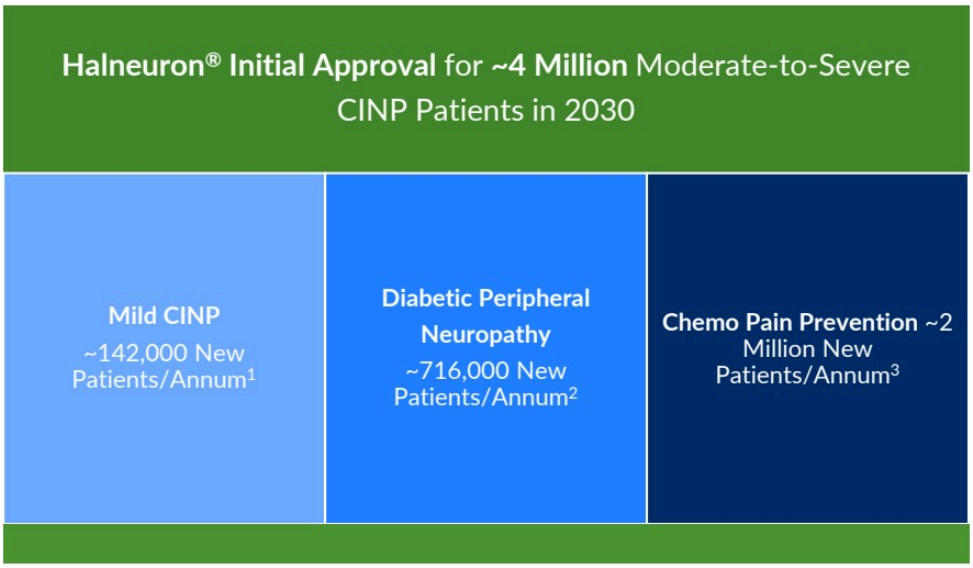
One-in-four (27%) Halneuron® responders had pain relief for >30 days after 4 days of treatment



Placebo response was temporary

A "Responder" was defined as a patient who had a mean reduction in pain intensity of ≥ 30%; or ≥ 50% reduction in opioid use

Halneuron® Offers Potential Relief for Millions of Pain Sufferers in the US Alone



1. Sreeram 2023; 2. CDC 2026, Current Diabetes 2026; 3. American Cancer Society 2026

Advantages of Synthetic Halneuron® 30 ug for Injection

- Scalability synthetic process not limited by raw material availability. Starting material is a common sugar
- Faster and greater control over the manufacturing process
- Absence of bioburden, largest impurity of natural TTX
- Toxicity enters in last step of >30 chemical transformations. High potency only for last step and purification
- A 1-gram synthesis represents 33,000 doses and we have recently completed 4 grams of GMP material
  - We are now on the path of commercialization of the route
- Utilizes robust purification technique (IP) developed for naturally sourced tetrodotoxin.
- New IP developed for purification of crude TTX and concentration of purified fractions filed in 2025
  - If granted, may give Composition of Matter and Process protection until 2046
  - Process for the Synthesis of Tetrodotoxin and Intermediates Thereof
  - Intermediates and Process for the Synthesis of Tetrodotoxin



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SP16 IV Therapy

Chemotherapy Induced Pain & Peripheral Neuropathy (CIPPN)

Program Overview

SP16 Mechanism Allows for Healing During Inflammation

A1AT Target

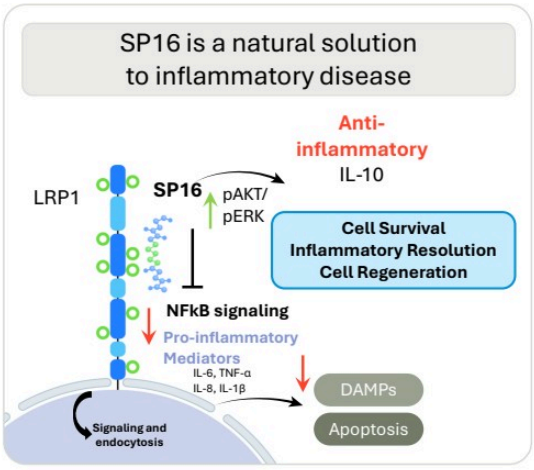
- A1AT (serine protease inhibitor family) regulates proteases to protect healthy tissue
- Dysregulated protease activity drives inflammation and tissue damage

SP16 Design

- 17–amino acid peptide derived from active region of A1AT
- Selectively activates LRP1 (LDL-receptor related protein 1) to drive anti-inflammatory and reparative signaling to restore immune balance

Hypothesized Outcomes:

- Anti-inflammatory: reduces IL-6, IL-8, IL-1β, TNF-α to decrease inflammation and pain
- Tissue repair: increases pAKT / pERK signaling to support cell growth

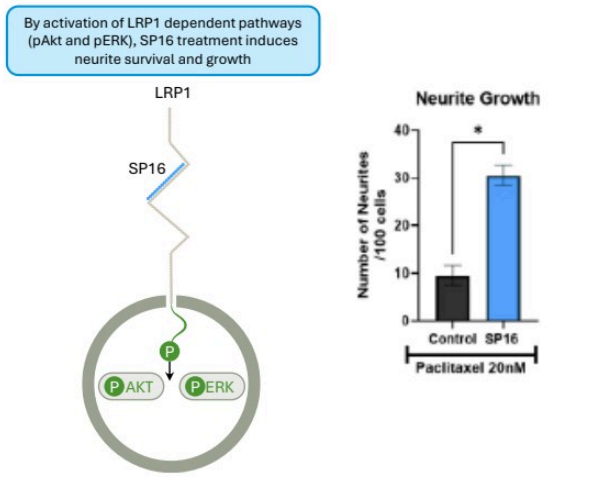


Dual mechanism anticipated to reduce inflammation while promoting tissue repair

SP16 LRP1 Agonism Exhibits Potential to Prevent and/or Repair Nerve Damage Associated with Chemotherapy

- In collaboration with Dr. Wendy Campana at the University of California San Diego, SP16 was tested for its regenerative effects on neurons
- Neurotrophic effects of SP16 and associated increase in regenerative genes in neurons (Wang, 2022)
- SP16 was neuroprotective, activating neurite survival and growth, pro-regenerative genes and proteins, and protective signaling pathways
- SP16 significantly increased neurite growth in the presence of paclitaxel

***Reparative Function of SP16**



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*Source: Wang et al., 2021 FASEB J

NCI Funded SP16 Research Plan to be Finalized with FDA and Executed at University of VA

Patient Population

Up to 32 Metastatic Cancer Patients Experiencing Neuropathy from their Concurrent Chemotherapy

UNIVERSITY of VIRGINIA

NIH NATIONAL CANCER INSTITUTE

SP16 IV Phase 1b



- SP16 Low Dose n=8
- SP16 Mid Dose n=8
- SP16 High Dose n=8
- Placebo n=8

Baseline Chemotherapy

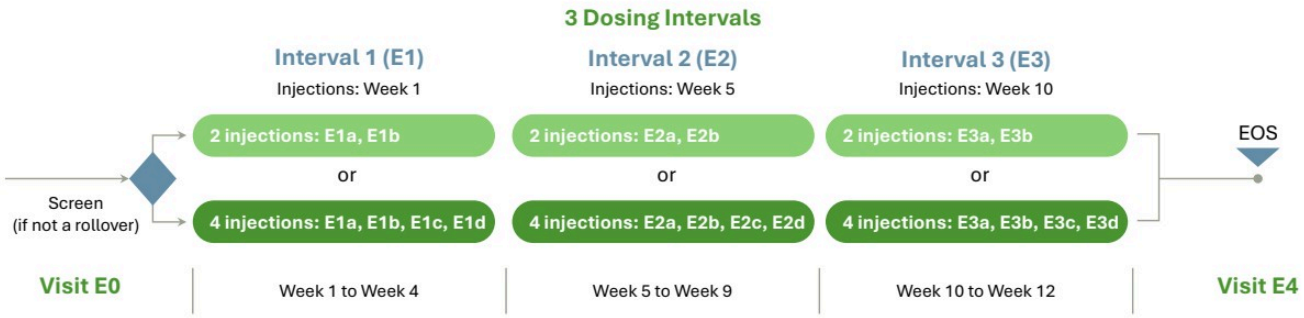
Phase 1b Study Endpoints

- SP 16 Safety
- SP 16 Prevention of CIPN
- SP16 Pharmacokinetics
- Chemotherapy Adherence

SP16 IV Phase 2a Eligible for NCI Funding

Open Label Extension Study Design

12 Week Open Label Study



- Patients will continue daily pain diaries entry scores
- IRT will assign either 2 or 4 injections for the interval, based on 7-day average pain scores
- Halneuron® dosing as follows:
  - NRS Pain Change > 4 gets 4 injections at treatment interval, or
  - NRS Pain Change < 3 gets 2 injections at treatment interval

Commenced Enrollment May 2026

A First-in-Class Approach to Pain and Neuropathy

The Problem of Neuropathic Pain

- Neuropathy includes chronic pain, numbness, tingling, and poor coordination, with significant impact on QoL
- ~3 million US patients suffer from painful chemotherapy induced neuropathic pain (CINP)
- Life-cycle management opportunity (mild CINP, CRP and DPN) expands to ~ 3 million additional US patients

Lead Assets Establish Beachhead

- Lead asset Halneuron® inhibits the Na_V 1.7 sodium channel critical for pain signaling
- SP16 activates LDL-receptor related protein 1 (LRP1) to drive pain reduction (anti-inflammatory) and reparative signaling to restore immune balance

Clinically Validated

- Halneuron® demonstrated statistically significant and durable pain reduction, with acceptable safety profile, in cancer and chemotherapy related clinical pain studies to date

2026 Catalysts

- Halneuron® poised to progress to Phase 3 development in CINP
- SP16 CIPPN Phase 1b enrollment anticipated Q1 2027

Significant Opportunity

- CINP treatment market $1B in US/UK/EU4/Japan, projected to increase to ~$3B by 2036[1]
- Expand into larger ~$7.5B Cancer Related Pain (CRP) market[2]

DOGWOOD THERAPEUTICS

[1]Delve Insight [2]Allied Market Research

Exhibit 99.3

DOGWOOD THERAPEUTICS

Halneuron® for the Treatment of Chemotherapeutic-Induced Neuropathic Pain (CINP)

November 2026

NASDAQ: DWTX

Forward-Looking Statements

Statements in this presentation contain “forward-looking statements,” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this presentation are forward-looking statements. Forward-looking statements contained in this presentation may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “suggest,” “target,” “aim,” “should,” "will," “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on the current expectations of Dogwood Therapeutics, Inc. (“Dogwood”) and are subject to inherent uncertainties, risks and assumptions that are difficult to predict, including risks related to the completion, timing and results of future clinical studies relating to Dogwood’s product candidates. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully in the section titled “Risk Factors” in the Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission. Forward-looking statements contained in this presentation are made as of this date, and Dogwood undertakes no duty to update such information except as required under applicable law.

Team Introductions

Experienced Leadership



Greg Duncan
Chairman & CEO
Pfizer · UCB · Celtaxsys



R. Michael Gendreau MD, PhD
Chief Medical Officer
Cypress · Intec Pharma



Angela Walsh
Chief Financial Officer
Altea Therapeutics · Celtaxsys



Ralph Grosswald
Senior VP, Operations
Emory Healthcare · Celtaxsys



Scott Millard
VP, Research
premier research · SCIREX



Jerry Evarts
VP, Manufacturing
Acerta Pharma · Calistoga Pharmaceuticals · Gilead

Proven Record of Drug Development & Commercial Success

Zoloft (sertraline HCl) · Lipitor (atorvastatin calcium) · Celebrex · Savella · Viagra · Aricept · Lyrica (pregabalin) · Cimzia (certolizumab pegol)

Investment Highlights

P value = 0.003
Primary endpoint met
≥50% pain reduction at Week 4

~2.5x
Responder rate vs. placebo
(23.3% vs. 9.2%)

~9M
U.S. survivors with painful CINP
(~3M US)

~$1.0B
Current CINP market
No FDA-approved therapy

High-Quality, Consistent Halneuron® Phase 2b Data

1. **Primary endpoint met with robust significance**
   23.3% vs. 9.2% of patients achieved ≥50% pain reduction at Week 4 (p=0.003); statistically significant at every weekly visit beginning at Week 1 (p=0.04)

2. **Consistent across secondary and sensitivity analyses**
   Demonstrated statistical significance on primary responder analysis at every visit and on Patient Global Impression of Change: Quality of Life (p=0.006), Neuropathic Pain (p=0.027), Numbness and Tingling (p=0.025)

3. **Well tolerated with durable benefit**
   95.8% study completion in both arms; AEs predominantly mild and mechanism-related; ~50% response in 12-week OLE; 57.7-day mean response duration in prior Phase 2 cancer pain study

Large, Underserved Market Opportunity

4. **Large and growing patient population**
   ~9 million cancer survivors suffer from CINP today, with ~3.3M new CINP cases each year

5. **~$1.0B spent today on inadequate off-label options**
   Alpha-2-delta agents (46%), SNRIs (25%) and opioids (14%) lead 7MM share despite CNS and addiction liabilities; no FDA-approved CINP therapy

6. **Differentiated, late-stage and protected asset**
   Peripherally acting NaV1.7 blocker with no CNS effects; most advanced NaV1.7 program (next-closest in Phase 1); New Halneuron® synthetic manufacturing process enables IP protection, if granted, to 2046

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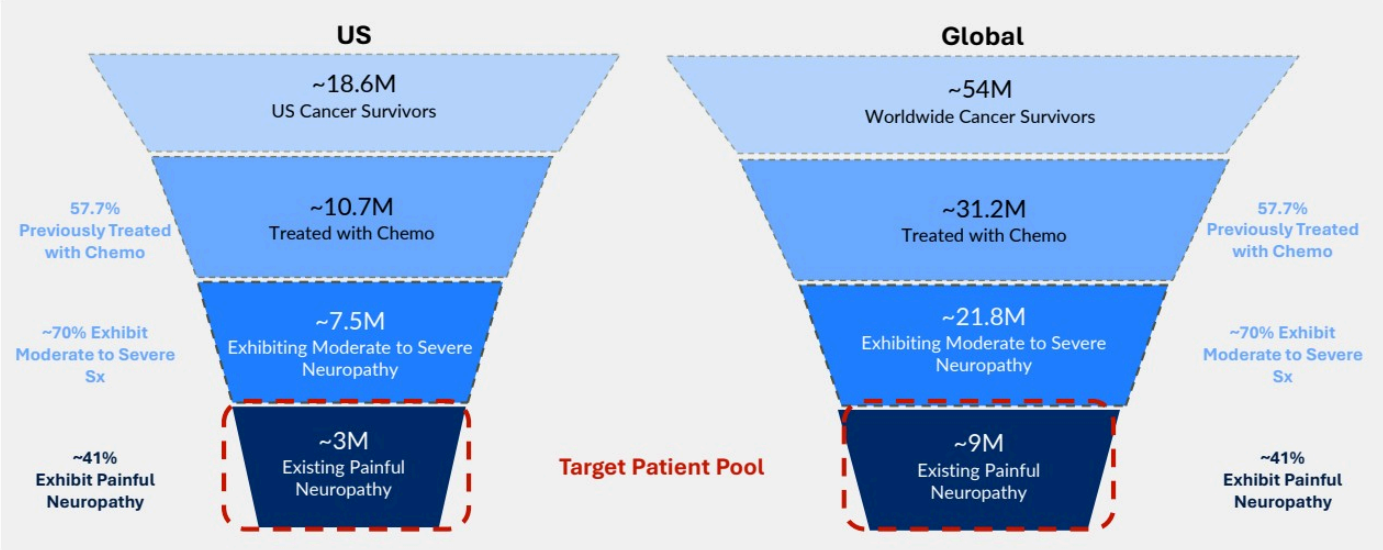
Sources: HAL-CINP-203 Phase 2b topline data; Delve Insight 2025; ACS Cancer Facts & Figures 2025. 7MM = 7 major markets; AE = adverse event; CNS = central nervous system; OLE = open-label extension; PGIC = Patient Global Impression of Change; SNRI = serotonin-norepinephrine reuptake inhibitor.

The Problem: CINP Patient Journey



Chemotherapy Induced Neuropathy Symptom Onset	Oncologist Pain Related Cancer Treatment Considerations	Pain Specialists Initial Commercial CINP Call Point	Oncologists Represent Market Development Opportunity
Patients Experience • Pain • Numbness • Tingling • Sensitivity to cold • Muscle weakness • Balance disturbance, and others	• **Mild Pain** – continue chemo + monitor • **Moderate Pain** – dose reduction/delay • **Severe Pain** – discontinue chemo	• Post chemo chronic pain patients referred to pain centers • Pain specialist (i.e. neurologist, anesthesiologists, etc.) treat "off-label" chronic pain meds (e.g. duloxetine, pregabalin, opioids)	• Oncologist treatment of pain represents a growth option • Buy and bill model aligns well for injectable treatments • LCM expansion to general cancer related pain

Moderate-to-Severe CINP Represents a Major Unmet Medical Need Today, Both in the US and Globally



Worldwide incidence of cancer is projected to grow by 53% by 2040

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Sources: ACS Cancer Facts & Figures 2025; Sreeram 2023; D'Souza 2025; BMJ, 2026; Anderer 2025; JAMA

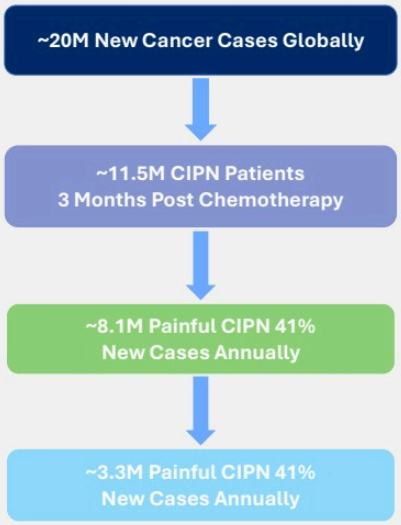
Projected US and Global Annual Increase in Moderate-to-Severe CINP Patient Pool

Annual Estimated Burden of New Cancer Type

Cancer Type	New Cases
Genital System	444,610
Digestive System	362,200
Breast	319,750
Respiratory	245,700
Urinary	170,470
Skin	112,690
Lymphoma	89,070
Leukemia	66,890
Oral & Pharynx	59,660
Endocrine	52,140
Other	44,280
Myeloma	36,110
Brain & Other Nervous	24,820
Soft Tissue	13,520
Total New	2,041,910



Annual Estimated Global Burden of CINP



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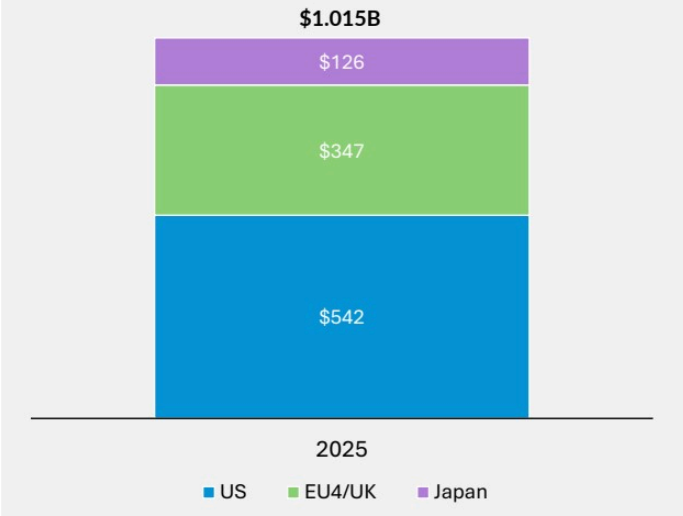
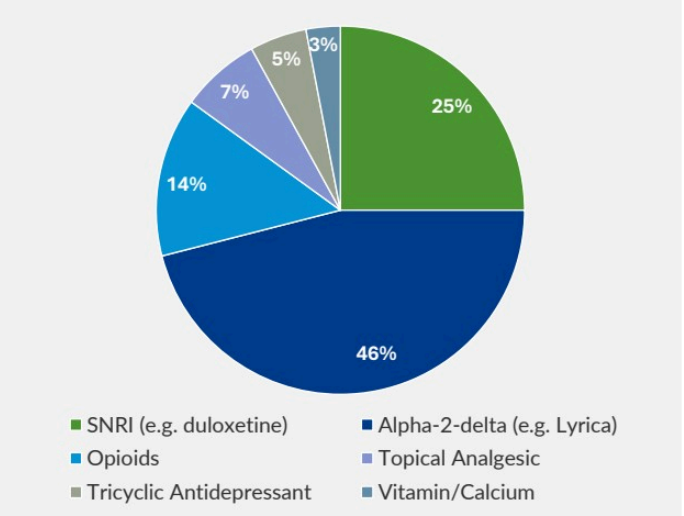
Sources: ACS Cancer Facts & Figures 2025; Sreeram 2023; D'Souza 2025; BMJ 2026

Significant CINP Treatment Market Across 7 Major Markets (7MM), Despite No FDA Approved Treatments

Total Market Sales ($M)



Market Share (%) by Therapy in the 7MM, 2026



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Source: Delve Insight, 2025

Our Solution - Halneuron®

Halneuron® is Tetrodotoxin (TTX), a voltage-gated sodium channel blocker and potent small molecule found in puffer fish and several other marine animals (not a peptide or protein)

- Prevents or relieves pain by interrupting nerve conduction
- Modulates pain transmission in the peripheral nerves, no CNS effects
- Administered as a sub-Q injection
- Halneuron® treatment has demonstrated statistically significant, durable pain reduction, with acceptable safety profile, in cancer and chemotherapy related clinical pain studies to date
- New synthetic TTX manufacturing patents, if granted, enable intellectual property protection to 2046



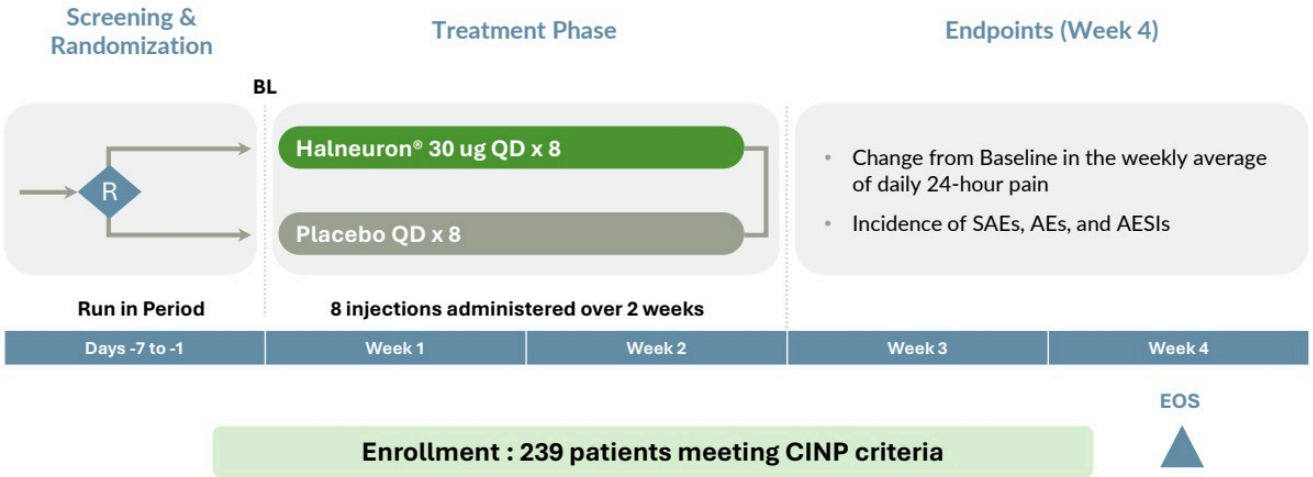
How Does Halneuron® Work?

- Halneuron® works as an analgesic by binding to the Nav1.7, channel, a sodium channel responsible for pain signal transmission
- Genetic Loss of NA_V 1.7 Function Leads to Congenital Insensitivity to Pain Syndrome



4-Week Phase 2b CINP Study

Primary Objective to explore the safety and efficacy of Halneuron® in the treatment of patients with moderate-to-severe CINP



Enrollment : 239 patients meeting CINP criteria

HAL-CINP-203: Disposition

Disposition	Halneuron®	Placebo	Total
Randomized	120	119	239
Completed	115 (95.8%)	114 (95.8%)	229 (95.8%)
Discontinued Early	5 (4.2%)	5 (4.2%)	10 (4.2%)
Discontinued Study due to AE	3 (2.5%)	2 (1.7%)	5 (2.1%)

Only **5 (2.1%)** of the patients who completed the study did not receive all 8 injections

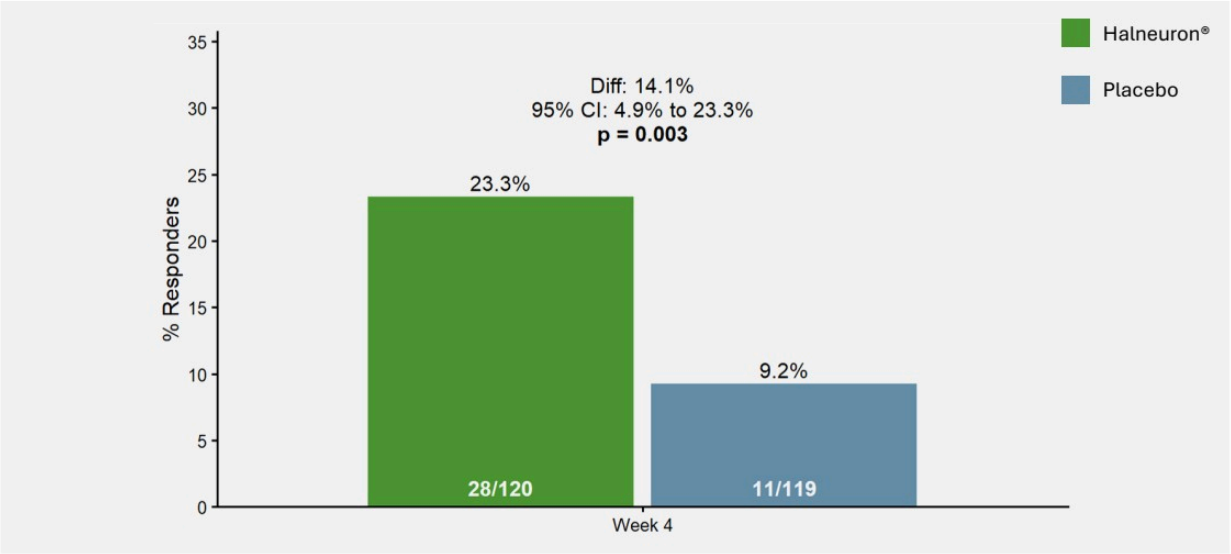
HAL-CINP-203: Baseline Characteristics

Characteristic	Halneuron® (N=120)	Placebo (N=119)
Age	65.4	64.9
% Female	83.3%	78.2%
Baseline Pain Score	6.1	6.0
On Any Concomitant Pain Medication	51.7%	57.1%
Duloxetine/TCAs	20.0%	21.8%
Gabapentinoids	39.2%	42.9%
Opioids	13.3%	10.9%
Years since CINP Onset	5.6	4.4
Prior Platinum Use	38.3%	42.0%
Prior Taxane Use	32.5%	34.4%
Prior Platinum and Taxane Use	29.2%	23.5%

Cancer Hx
49% Breast
26% Colorectal
6% Ovarian
5% Pancreas
4% Lung
10% Other

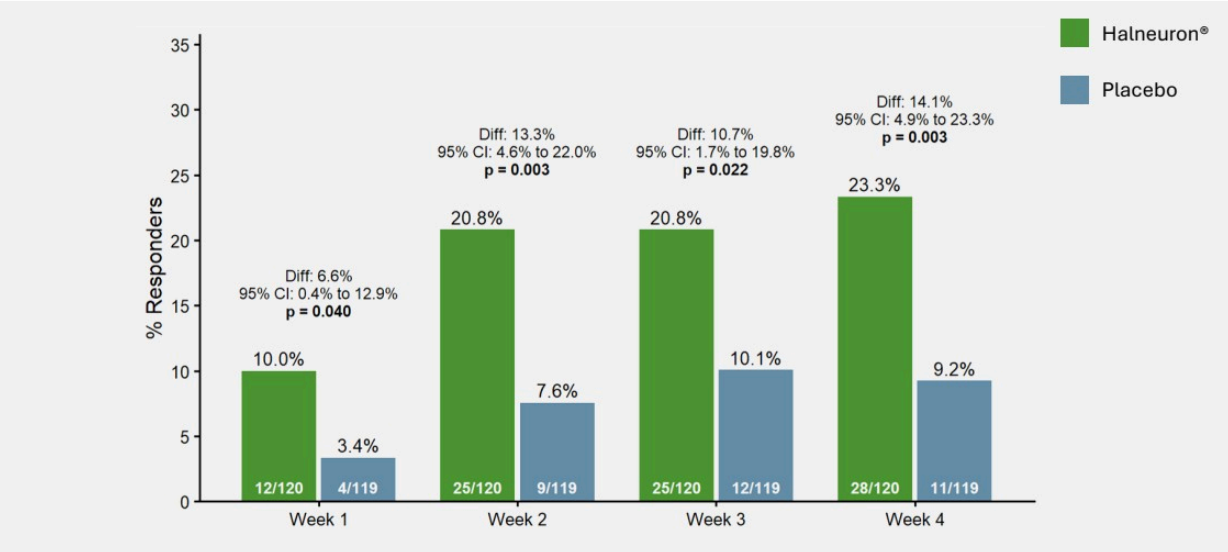
Primary Endpoint: 50% Responder Analysis for Pain Intensity

Proportion of Patients who achieved ≥50% Reduction at Week 4 from Baseline in Average Weekly Pain Intensity



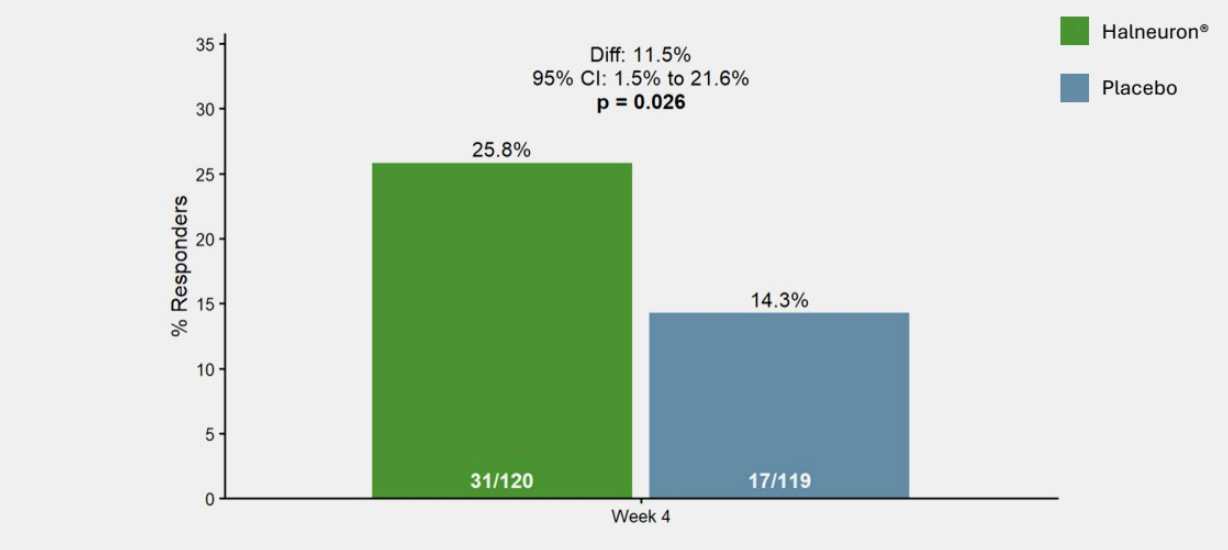
Primary Endpoint: 50% Responder Analysis By Week

Proportion of Patients who achieved ≥50% Reduction from Baseline in Average Weekly Pain Intensity



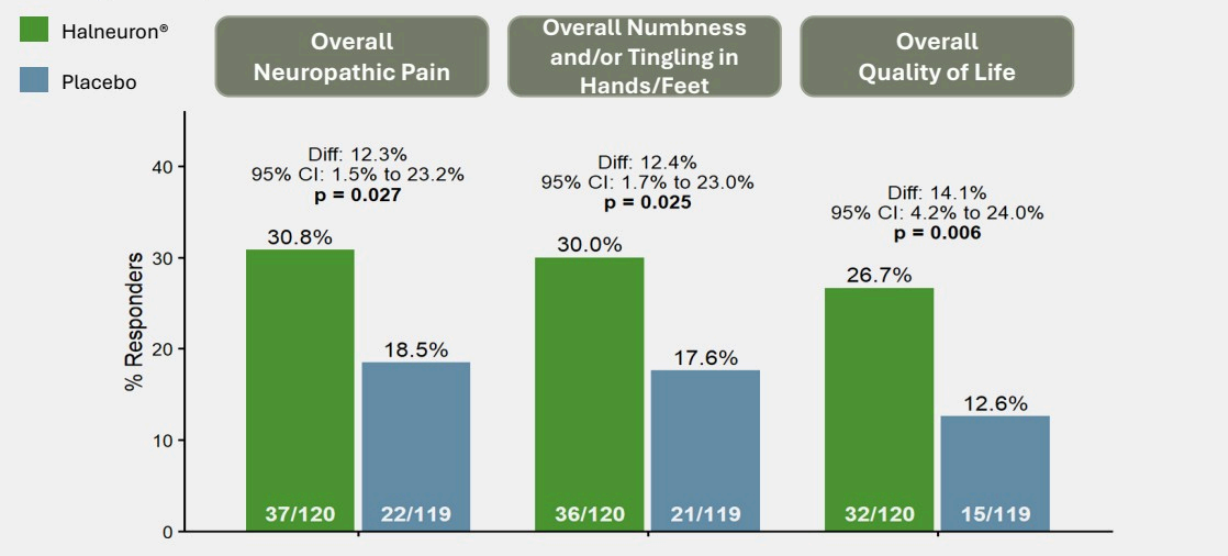
50% Responders: Pain Interference

Proportion of Patients who Achieved ≥50% Reduction from Baseline in Average Weekly Pain Interference at Week 4



PGIC Responder Analysis (Very Much or Much Improved)

Secondary Endpoint



1 Very Much Improved	2 Much Improved	3 Minimally Improved	4 No Change	5 Minimally Worse	6 Much Worse	7 Very Much Worse

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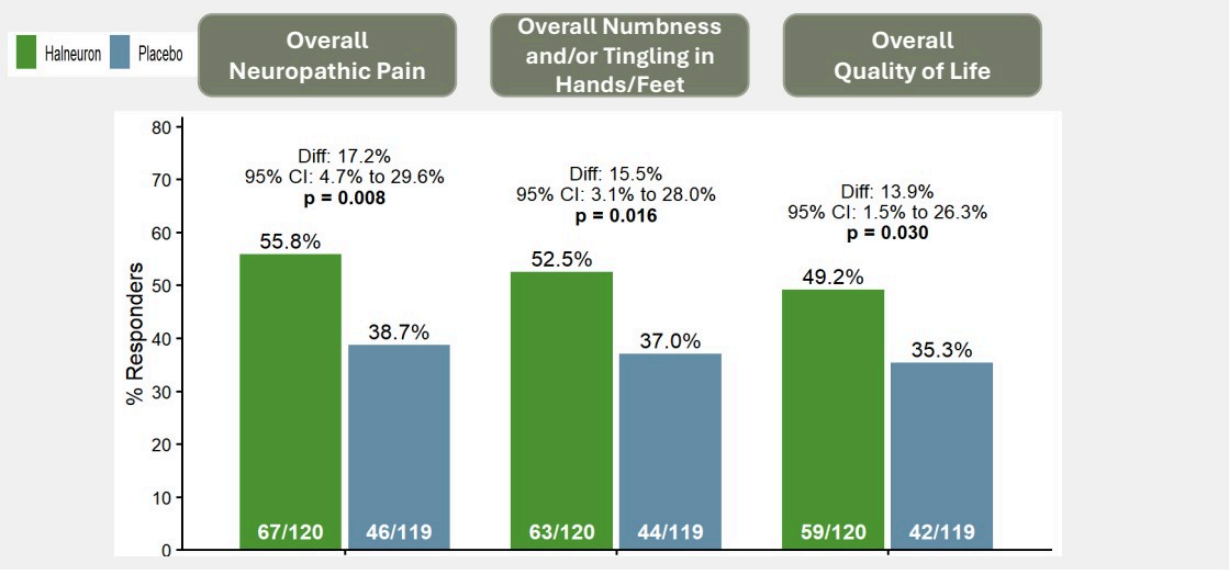
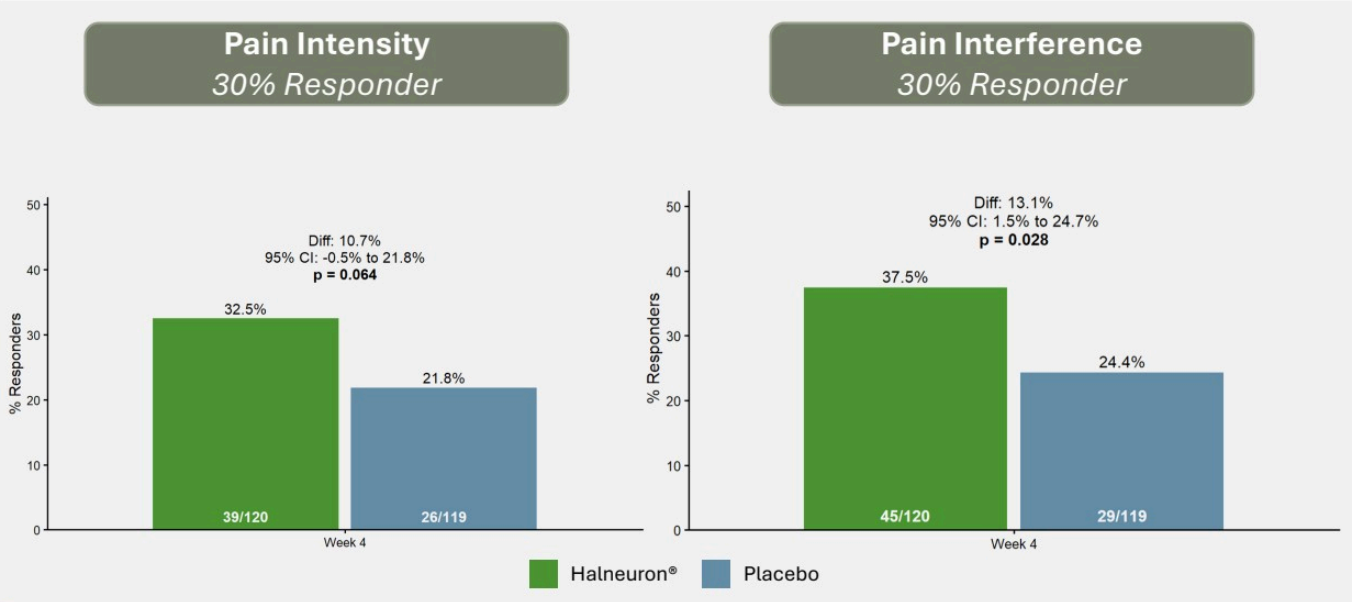
PGIC Responder Analysis (Any Improvement)

Secondary Endpoint



30% Responders: Pain Intensity and Pain Interference

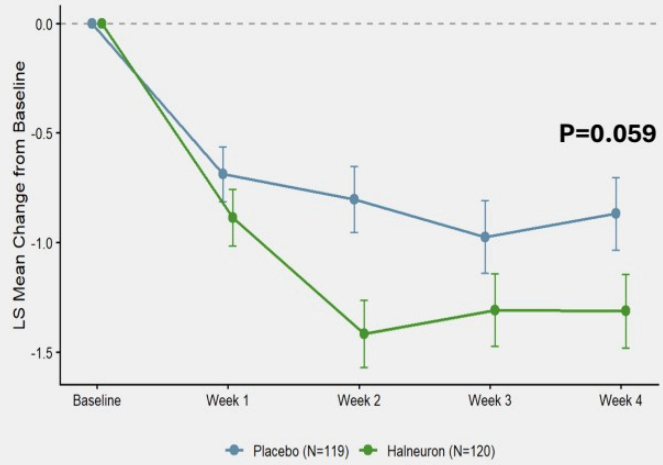
Secondary Endpoint



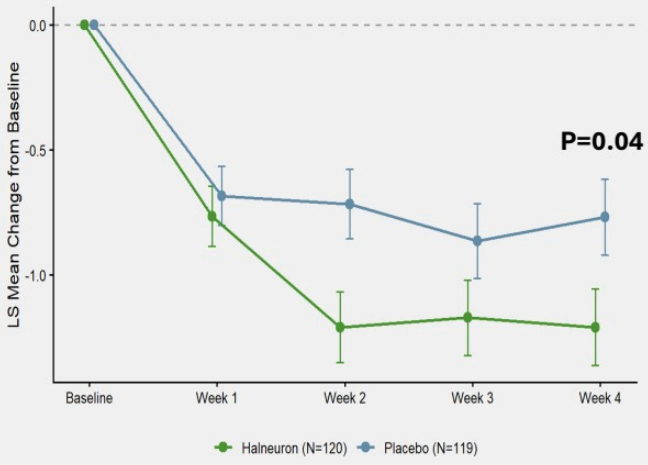
Group Mean Change from Baseline MMRM

Secondary Endpoint

Pain Intensity



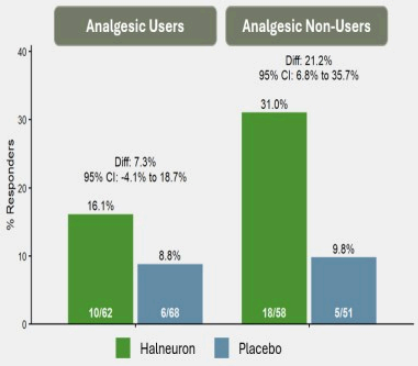
Pain Interference



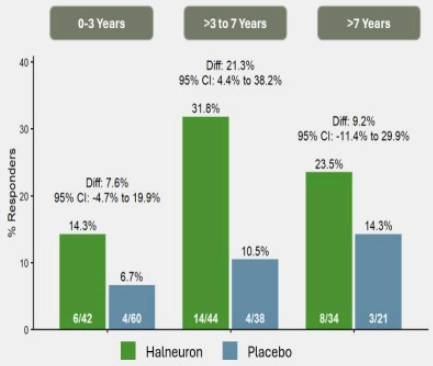
Error bars represent standard error of the LS mean

Subset Analysis of Primary Endpoint

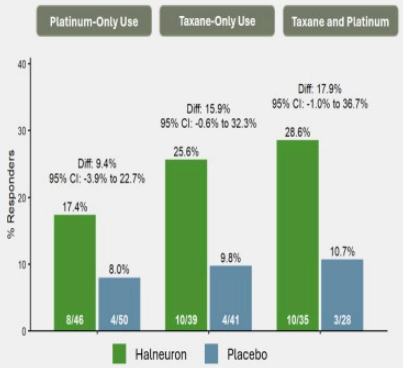
By Concomitant Analgesic Medication Usage



By CINP Duration



By Chemotherapy Type



Treatment-Emergent Adverse Events

≥5% with Halneuron® and Higher than Placebo

TEAE Preferred Term	Halneuron® (N=120)	Placebo (N=119)
Paraesthesia oral (lips, tongue, mouth tingling)	70.0%	7.6%
Hypoesthesia oral (numbness in oral cavity)	35.0%	1.7%
Paraesthesia	23.3%	8.4%
Headache	15.8%	9.2%
Nausea	15.0%	6.7%
Hypoesthesia	11.7%	2.5%
Fatigue	9.2%	1.7%
Dizziness	8.3%	3.4%
Blood pressure increased	6.7%	0.8%
Dysgeusia (taste distortion)	6.7%	1.7%
Somnolence	5.8%	0.8%

Details on Paraesthesias and Hypoesthesias in Halneuron® Group

Event type	% Halneuron® Participants with Event	Severity			Duration in Hours Median (IQR)
		Mild	Moderate	Severe	
Paraesthesia oral	70.0%	99.6%	0.4%	0%	2.3 (1.2 to 3.8)
Hypoesthesia oral	35.0%	99.0%	1.0%	0%	2.2 (1.2 to 3.6)
Paraesthesia	23.3%	99.5%	0.5%	0%	2.2 (0.9 to 4.0)
Hypoesthesia	11.7%	100%	0%	0%	3.2 (2.1 to 4.7)

Details Two SAEs

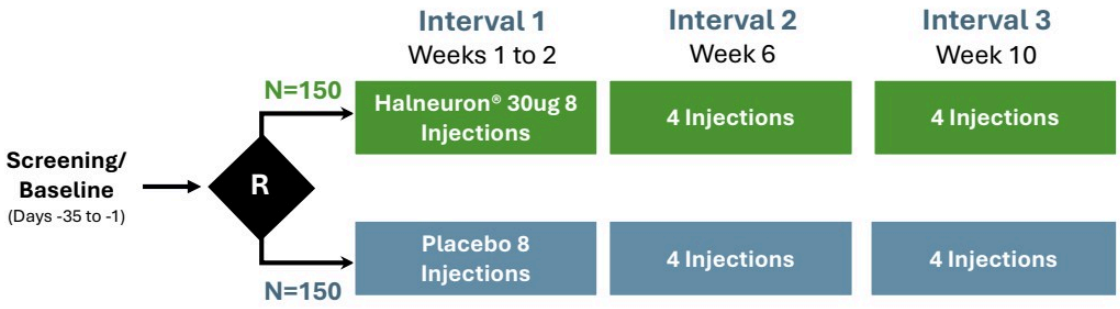
- **Two SAEs**
  - 102-002 - 78 year-old female; AE verbatim term: Syncope
    - SAE occurred 12 days after last injection while patient at physical therapy
    - Moderate, unlikely related (according to investigator); history of hypertension & severe valvular heart disease; Recovered same day
  - 110-001 - 48 year-old female; AE verbatim term: Rapid heart rate
    - Occurred at Visit 8 while patient in office for injection #8 (which was skipped due to SAE). No issues with previous 7 injections; patient continued in study and completed
    - Moderate; possibly related (according to investigator); however, history of supraventricular tachycardia (SVT) and paroxysmal SVT since 2021. SAE resolved by next day

Consistently Achieved Statistical Significance Across Multiple Endpoints, with Favorable Tolerability

Endpoint at Week 4	2-sided p-value
≥50% responder on pain intensity	0.003
≥50% responder on pain interference	0.026
≥30% responder on pain intensity	0.064
≥30% responder on pain interference	0.028
LS mean change from baseline in pain intensity (MMRM)	0.059
LS mean change from baseline in pain interference (MMRM)	0.040
PGIC (much or very much improved)	
Neuropathic pain	0.027
Numbness or tingling	0.025
Quality of life	0.006
PGIC (any improvement)	
Neuropathic pain	0.008
Numbness or tingling	0.016
Quality of life	0.030
Halneuron® overall discontinuation rate	**4.2%**
Halneuron® discontinuation rate due to AE	**2.5%**

Proposed Design for Halneuron® 30ug Phase 3 Studies

12-Week, Randomized, Placebo-Controlled Trial



Primary Endpoint
50% Responder on Pain Intensity at Week 12

Assumptions

- Consistent with 12-week Special Protocol Assessment previously agreed upon with FDA
- Sample size based on treatment effect sizes from Phase 2b
- Interim analysis with 50% of participants evaluable
- Conducted exclusively in the US

Next Steps: Path to Halneuron® 30 ug Phase 3 and NDA

Phase 3 Design: Two 12-week, placebo-controlled US studies (n=150/arm) | 8 + 4 + 4 injections | Primary endpoint: ≥50% responder at Week 12



Key Next Steps

1. **FDA End-of-Phase 2 meetings:** confirm Week 12 ≥50% responder endpoint, Phase 3 design (consistent with prior SPA) and CMC / PK bridging plan
2. **Initiate US Phase 3 Study 1 (Q3'27):** interim analysis expected 2028
3. **US Phase 3 Study 2 (Q2'28):** potentially not required if FDA accepts a single pivotal study
4. **NDA submission:** targeted for Mid-2030
4. **Breakthrough submission:** targeted Q1

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Note: Timeline and cost estimates are company projections. Dashed bar denotes study that may not be required. CMC = chemistry, manufacturing and controls; EOP2 = End-of-Phase 2; OLE = open-label extension; PK = pharmacokinetic bridging study; SPA = Special Protocol Assessment.